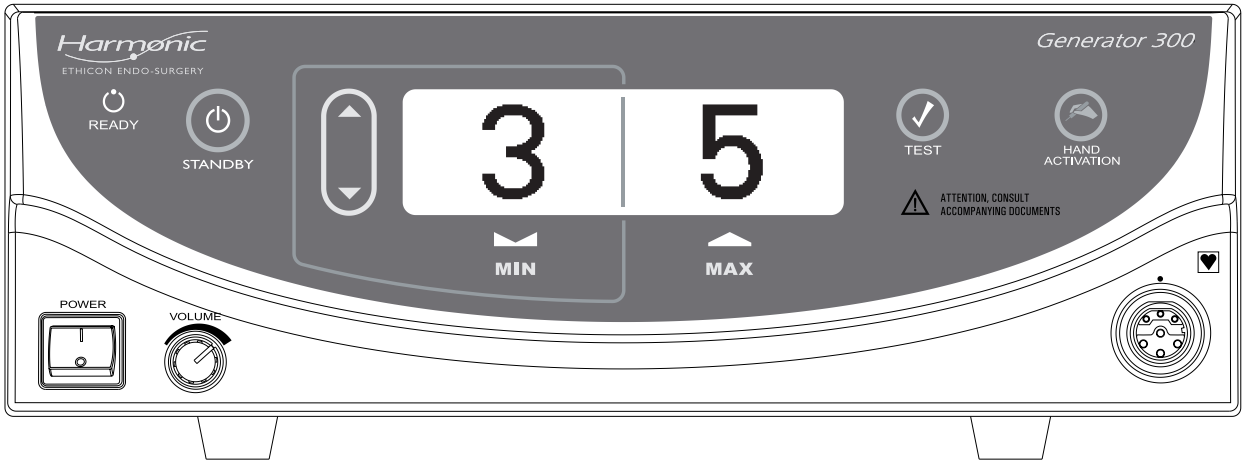
Harmonic® *



Generator 300 System Service Manual

*Formerly known as *UltraCision*® *Harmonic Scalpel*®

Harmonic, UltraCision and Harmonc Scalpel are tradmarks of Ethicon Endo-Surgery.

ETHICON ENDO-SURGERY, LLC
a Johnson & Johnson company

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Scope

This manual and the equipment it describes are for use only by qualified Biomedical Service Personnel. It is intended only as a guide for technical maintenance of the HARMONIC® Generator 300 System.

This manual is intended to be a companion to the HARMONIC Generator 300 System User Manual. A thorough understanding of the User Manual is required to properly understand and use the information in this service manual.

Installation Guidelines

The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the instructions in this and the HARMONIC Generator 300 System User Manual. The inspection shall be documented along with any test results to demonstrate proper installation.

Ethicon Endo-Surgery reserves the right to change the electrical/electronic or mechanical configurations and components without notice. Schematic revisions may not match PCB revisions in the unit being maintained; consult Ethicon Endo-Surgery before making any changes. When necessary, amendments to this manual will be made available by request only.

Product Information

Product Name: HARMONIC Generator 300 System (formerly known as ULTRACISION® HARMONIC SCALPEL® Generator 300 System)

Model Number/Product Code: GEN300/GEN04
Voltage: 100 – 240 VAC

This manual is subject to revision. When referring to this manual please include the following:
Document Type: Service Manual
Document Number: P40401P0X (on back cover of manual)

Manufactured by:
Ethicon Endo-Surgery, LLC
Guaynabo, Puerto Rico 00969 USA
1-800-USE-ENDO (U.S.Customers)
http://www.harmonicscalpel.com

Service

1-800-USE-ENDO (U.S. Customers)
Customers outside the U.S. should contact their Ethicon Endo-Surgery representative for assistance.

- This equipment, in conjunction with the accessories, is intended to produce high-frequency mechanical energy which enables hemostatic cutting and/or coagulation of soft tissue.
- Safe and effective ultrasonic surgery is dependent not only upon equipment design, but also, to a large extent, upon factors under control of the user. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.
- The HARMONIC Generator 300 System, including the hand piece, is not Magnetic Resonance safe and is not Magnetic Resonance compatible.
- Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. It is possible to create sparks by hitting other metal instruments. Sparks may ignite flammable gases such as bowel gas.
- The HARMONIC Generator 300 System must be operated within the required ambient operating conditions. Refer to Chapter 14 – System Specifications.
- The HARMONIC Generator 300 System should be tested on a periodic basis by qualified biomedical maintenance personnel to ensure proper and safe operation.
- Refer all servicing to qualified biomedical personnel. Your Ethicon Endo-Surgery representatives are available to assist in having your equipment serviced.
- Removing the top cover of the generator unit may expose the user to parts within the generator unit which may have high surface temperatures and high voltage. These surfaces are potentially dangerous and should be treated with extreme caution.
- Always unplug the generator from the wall outlet prior to opening the cover for servicing. This poses a potential electric shock hazard.
- After removing the cover, inspect the internal components for obvious damage or foreign debris. Never power ON a suspected problem unit.
- Never remove or install any parts with power on.
- The active blade of a HARMONIC instrument heats the tissue by friction and is intended to supply sufficient friction and shearing effect to cut and coagulate tissue in contact with the active blade. As a result, the user should use caution with the blade, clamp arm, and distal part of the shaft as they may exhibit an elevated temperature. Additional temperature information may be contained in individual instrument instructions for use.
- The user should verify that the power receptacle with which this unit is used is properly grounded and is correctly polarized. Do not use ground cheater plugs or extension cords. Do not connect the HARMONIC Generator 300 System to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle. (Refer to Chapter 14 – System Specifications.)
- Verify that the outlet voltage correctly corresponds to the generator's requirements. (Refer to Chapter 14 – System Specifications.) Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

- Do not connect the HARMONIC Generator 300 System to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle.
- Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.
- Do not place liquid containers on top of the unit. Wipe spilled liquids off the unit immediately. To avoid inadvertent penetration of liquids, do not operate this unit in a tilted position.
- Locate the HARMONIC Generator 300 System, including the hand piece cable, at least 3 ft. (approximately 1 m) from electrosurgical systems and their hand piece (e.g., pencil) cables. The generator should not be on the same circuit as other equipment and machines. Please note that different outlets may not necessarily mean different circuits.
- To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.
- Use proper electrical safety and hospital procedures when working on the generator unit.
- The AC mains voltage presents a shock hazard and is accessible when the generator cover is removed. Caution must be used near internal system components, which attach directly to the AC mains such as the power entry module, mains fuses, power switch, and open-frame 48V power supply.
- It is hazardous to connect non-isolated probes to specific isolated sections of the generator. Doing so may introduce a high voltage from the hand piece to earth ground and produce a shock hazard.
- Refer to all other HARMONIC System documentation to review operating procedures.

Notes

- Use only Ethicon Endo-Surgery approved replacement parts. Contact the Ethicon Endo-Surgery representative for assistance in obtaining replacement parts by calling 1-800-USE-ENDO for customers in the United States. Customers outside the U.S. should contact their Ethicon Endo-Surgery representative for assistance.
- Minimizing operating temperature and extreme thermal cycles will extend the life of the equipment.
- Throughout this manual "instrument(s)" refers to the HARMONIC Generator 300 System blades, ball coagulators, or coagulating shears.

System Description

The HARMONIC Generator 300 System utilizes ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue. The system consists of an ultrasonic generator, a foot switch, an optional hand switching adaptor, a hand piece, and a variety of open and minimally invasive instruments.

Note: Throughout this manual "instrument(s)" refers to the HARMONIC Generator 300 System blades, ball coagulators, or coagulating shears.

The HARMONIC instruments vibrate longitudinally at 55.5 kilohertz. This ultrasonic vibration at the blade enhances its cutting ability. The same vibration seals small vessels with coagulated blood and tissue proteins. Hemostasis occurs when tissue couples with the instrument. This coupling causes collagen molecules within the tissue to vibrate and become denatured, forming a coagulum.

Note: Refer to package inserts provided separately for information about the Hand Piece, Hand Switching Adaptor, Test Tip and Instruments prior to using the system.

Indications

The HARMONIC Generator 300 System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The HARMONIC Generator 300 System instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels.

Contraindications

- The instruments are not indicated for incising bone.
- The instruments are not intended for contraceptive tubal occlusion.

System Components

Generator 300

The generator supplies the hand piece with electrical energy and facilitates selection of power levels, system monitoring, and system diagnostics.

Power is delivered by activating the foot switch or hand switching adaptor.

Hand Piece

The hand piece contains an acoustic transducer that converts the electrical energy supplied by the generator to mechanical motion. The transducer is connected to an ultrasonic wave guide/amplifier which amplifies the motion produced by the transducer and relays it to the instrument.

Instrument

The mechanical motion from the hand piece advances to the instrument, transmitting ultrasonic energy which enables hemostatic cutting and/or coagulation of tissue.

Power Levels

The generator delivers two power levels: minimum (MIN) and maximum (MAX). The minimum power level may be adjusted by the user from Level 1 to 5. The maximum power level is always Level 5. With all instruments except the ball coagulator, use a higher generator power level for greater tissue cutting speed and a lower generator power level for greater coagulation. For the ball coagulator, higher generator power levels will provide greater coagulation. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors including the power level selected, instrument characteristics, grip force (when applicable), tissue tension, tissue type, pathology, and surgical technique.

Note: Refer to the instruments' package inserts for additional power level information.

The HARMONIC Generator 300 System consists of the following components: Generator (GEN04), hand piece, instruments, foot switch, and hand switching adaptor (if used). The generator produces an electric signal, which is transmitted via a coaxial cable to the hand piece, which then converts the electrical signal into ultrasonic, mechanical motion.

Hand Piece
The hand piece houses several major components that generate, amplify, and deliver ultrasonic energy to the instrument end-effector. When each component is attached to the other and tuned, an acoustic drive train is formed. Two key parts of the acoustic system or acoustic drive are:

Acoustic Transducer: Converts the electrical energy into motion. When an AC waveform is applied to the transducer, the piezoelectric material expands and contracts to produce longitudinal motion.

Instrument: Couples the ultrasonic energy to the tissue and amplifies motion. In a laparoscopic configuration, the instrument is elongated by means of a "Laparoscopic Extension." This extension allows the ultrasonic energy to propagate from the hand piece to the instrument with minimal loss.

Generator
The generator converts the AC line voltage to a controlled DC level. The DC level is then modulated at the resonant frequency of the hand piece. The modulated signal is then filtered and delivered to the hand piece, where it resonates the acoustic drive train. A more detailed description follows.

Power Entry Module: Accepts a standard, hospital grade utility cord. Refer to Chapter 14 – System Specifications for details. Provides susceptibility filtering from the external environment as well as suppressing electromagnetic emissions produced by the generator that could be conducted back through the power cord.

Power Supply: Provides 48 VDC to DC/DC Converter and Current/Power Regulation Circuit.

Current and Power Regulation Circuit: Provides Current/Power regulation. Current limit circuits protect these assemblies and others from overload conditions.

Patient Isolation Circuit: Provides a safety isolation barrier to patient and/or user. The voltage generated on the secondary of the transformer is isolated from the primary and thereby not referenced to earth ground.

Microprocessor: The microprocessor contains the software program that drives the HARMONIC Generator 300 System. The software provides the user interface, frequency drive signal, as well as drive signals to the Liquid Crystal Display, front panel indicators, and generator audio circuit.

Liquid Crystal Display and Front Panel: The Liquid Crystal Display and front panel indicators report the operating mode of the HARMONIC Generator 300 System. They are driven by the microprocessor.

Foot Switch and Hand Switching Adaptor
Foot Switch(es): The foot switch(es) allow(s) the user to activate the system in either the minimum (MIN) or maximum (MAX) modes based on which foot pedal is being pressed. Pedal activations are communicated to the microprocessor.

Hand Activation Circuit: The hand switching adaptor allows the user to activate the system in either the minimum (MIN) or maximum (MAX) modes based on which button is being pressed. Hand activations are communicated to the microprocessor.

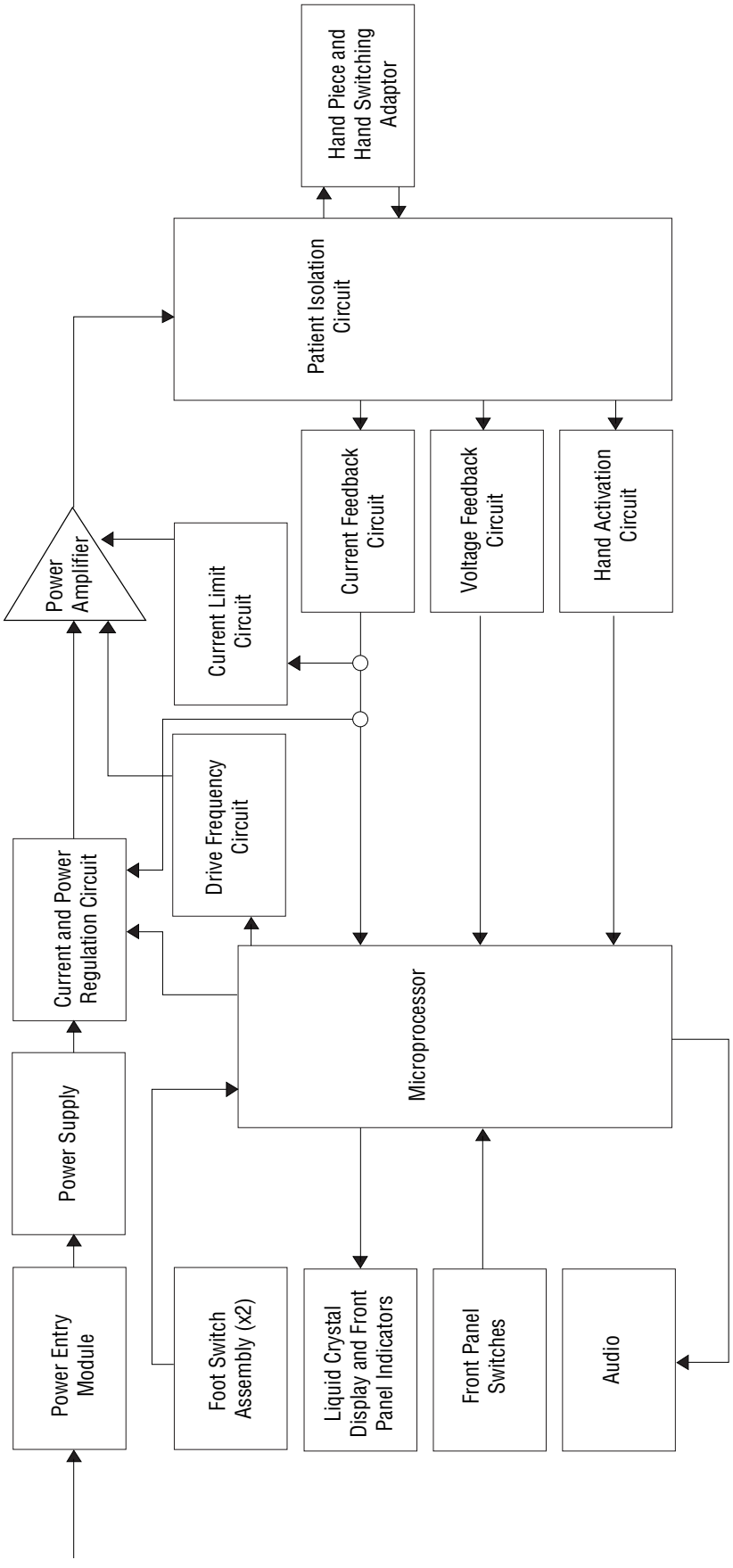


Fig. 3-1 Block Diagram

Unpacking Instructions

The HARMONIC Generator 300 System includes several components that are purchased separately. Upon receiving the ordered components, check for visible shipping damage. Do not attempt to use any component if it appears damaged. If damage is seen, contact your Ethicon Endo-Surgery representative.

Note: The original packaging should be saved for future storing and/or transporting of the device. Warranty may be voided if the unit is not returned to the service center in the original packaging or equivalent packaging which will protect the unit from damage during shipment.

System components may include the following parts (for product codes, see Chapter 14 – System Specifications):

Generator 300 - includes the generator, power cord, user manual, and service manual.

Note: The User Manual includes a troubleshooting guide (see back pocket of manual binder). Remove the self-adhesive guide's backing and adhere the guide to the top panel of the generator. Placement guides for the Troubleshooting Guide are found on the generator's top panel.

Foot Switch - includes the foot switch and detachable cable assembly.

Note: The foot switch is required if the system will be used with coagulating shears or instruments that are not compatible with the hand switching adaptor. Since the generator has receptacles for two foot switches, two foot switches may have been shipped.

Cart - the cart is optional. It is designed to hold one HARMONIC Generator 300 unit. The cart requires assembly; instructions are included with the cart.

Initial Setup

1 Confirm that the generator power switch is OFF during setup.

Caution: The active blade of a HARMONIC instrument heats the tissue by friction and is intended to supply sufficient friction and shearing effect to cut and coagulate tissue in contact with the active blade. As a result, the user should use caution with the blade, clamp arm, and distal part of the shaft as they may exhibit an elevated temperature. Additional temperature information may be contained in individual instrument instructions for use.

2 Secure the generator on its cart or on another suitable fixture. To secure the generator on its cart, place the generator's rubber feet into the corresponding holes on the cart. Push down on the generator's top panel.

Caution: To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.

Warning: The HARMONIC Generator 300 System must be operated within the required ambient operating conditions. (Refer to Chapter 14 – System Specifications for requirements.)

3 Connect the line cord into the AC inlet located on the generator's rear panel and into an appropriately-grounded outlet. If the power cord is wrapped around the cart handle, it must be completely removed from the cart handle prior to plugging it into the power outlet.

Warning: Verify that the outlet voltage correctly corresponds to the generator's requirements (Refer to Chapter 14 – System Specifications). Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

Caution: Do not connect the HARMONIC Generator 300 System to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle.

4 **a.** Attach the foot switch cable to the foot switch:

Note: Although installation of the foot switch is optional when using the hand switching adaptor, installing the foot switch is recommended in case its use is needed during the procedure.

- Confirm that the connector and receptacle are dry and clean.
- Orient the slot on the foot switch cable's larger connector at 12 o'clock.
- Seat the connector in the foot switch receptacle.
- Turn the connector collar clockwise until tight. Ensure the collar is finger-tight to prevent inadvertent activation that may result from fluid ingress.

b. Connect the foot switch cable's smaller connector to the foot switch receptacle on the rear panel of the generator.

- Confirm that the connector and receptacle are dry and clean.
- Align the red dot on the foot switch 4-pin connector with the red dot on the 4-pin receptacle on the generator back panel.

Note: The generator has two identical foot switch receptacles. If one foot switch is used, either receptacle may be used.

Repeat steps 4a and 4b if a second foot switch will be used.

5 Connect the instrument and adaptor (or hand switching adaptor), if required, to the hand piece following instructions in their package inserts.
Note: The hand switching adaptor must be at room temperature to function properly. Do not immerse in water to cool rapidly. After steam sterilization, allow hand switching adaptor to air cool for at least 15 minutes prior to use.

6 Connect the hand piece connector to the receptacle on the front panel. Align the white dot on the connector with the white dot on the generator. Ensure the hand piece connector is clean and dry before connecting the hand piece to the generator. Fully insert the hand piece connector to assure complete, proper connection to the generator. (To disconnect the hand piece, firmly grasp the connector and pull the connector away from the generator.)

7 Turn the generator power switch on and observe the power-up sequence. During power-up, the following indicators on the front panel will briefly illuminate:

- **READY, STANDBY, MIN, MAX, TEST, ATTENTION, HAND ACTIVATION**

The system will run its start-up sequence and display the software version. An audible tone will sound during the initiation sequence.

Note: The entire power-up initiation sequence should not exceed ten seconds.

If the start-up sequence deviates from the description above, contact qualified service personnel following hospital protocol.

When the initiation sequence is complete, the system will go to Standby. If the system senses a generator, hand piece, or instrument fault during use, an audible alarm (tone with long pulses) will sound and a visual alarm indicator will appear on the control panel. (Refer to Chapter 9 – High-Level System Troubleshooting or the Troubleshooting Guide located on top of the generator unit to resolve the problem.)

Controls, Indicators, and Connections

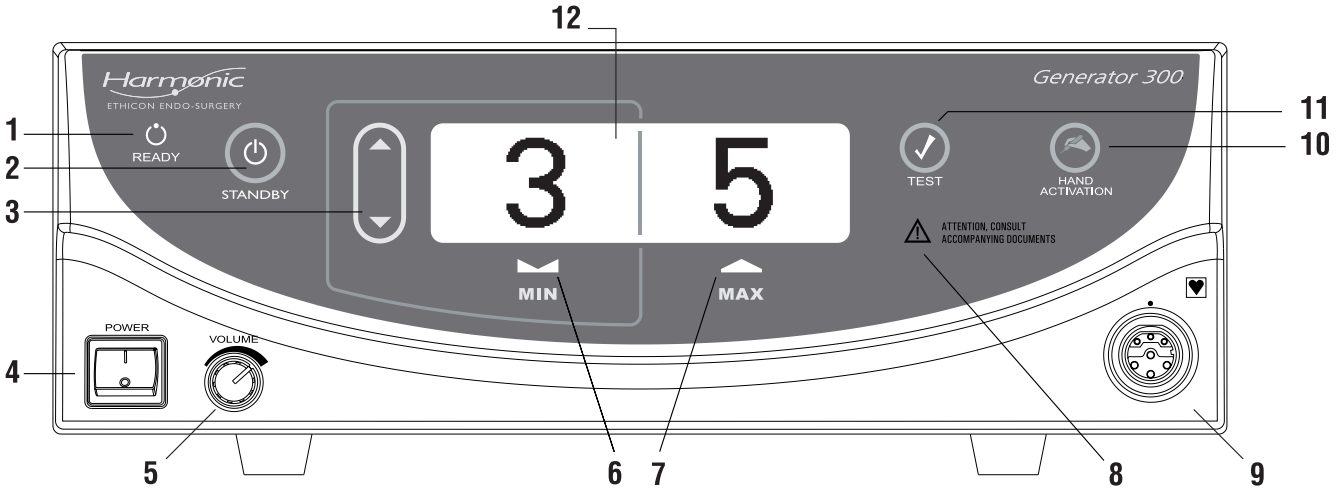


Fig. 5-1 Front Panel

1	**READY**	When this indicator is green, the system is ready for activation. Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.
2	**STANDBY**	Push this button to toggle between Standby and Ready modes. In Standby mode, this button, and the STANDBY icon, light up and all power is removed from the hand piece. Both the foot switch and hand switch are disabled. Upon power-up, the system defaults to Standby mode enabled.
3	**INCREASE/ DECREASE POWER LEVEL**	Push this button to increase or decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the graphic display. The power level may be adjusted when the generator is in Ready or Standby mode.
4	**POWER**	This switch controls the main electrical power to the generator.
5	**VOLUME**	Turn this knob to adjust the volume of the activation tones. A tone will sound indicating the volume level selected.
6	**MIN**	Indicates the user-settable MIN power level setting. When this power level is activated (by foot switch or hand switch), the MIN indicator will flash. On power-up the system defaults to MIN power level 3. Refer to the instruments' package inserts for the recommended MIN power level.
7	**MAX**	Indicates the maximum power level setting. This setting is always "5". When this power level is activated (by foot switch or hand switch), the MAX indicator will flash.
8	**ALARM INDICATOR**	This red indicator appears only if a system alarm occurs in response to a component or generator problem.

9	**HAND PIECE RECEPTACLE**	This receptacle is used to connect the hand piece to the generator.
10	**HAND ACTIVATION**	When the indicator is green, hand activation on the hand switching adaptor is enabled. To disable the Hand Activation mode, depress the button. Upon power-up, the system defaults to Hand Activation mode disabled. Note: If the foot switch is installed, the foot switch is always enabled.
11	**TEST**	Depressing this button initiates the Test mode. This mode is used during troubleshooting. The generator will emit a tone when the Test mode is active and "TEST IN PROGRESS" will appear on the display.
12	**GRAPHIC DISPLAY**	In Ready or Standby modes, this display indicates the minimum (user-settable level 1 to 5) and maximum (level 5) power levels. If a system or component problem exists, error codes will appear on this display.

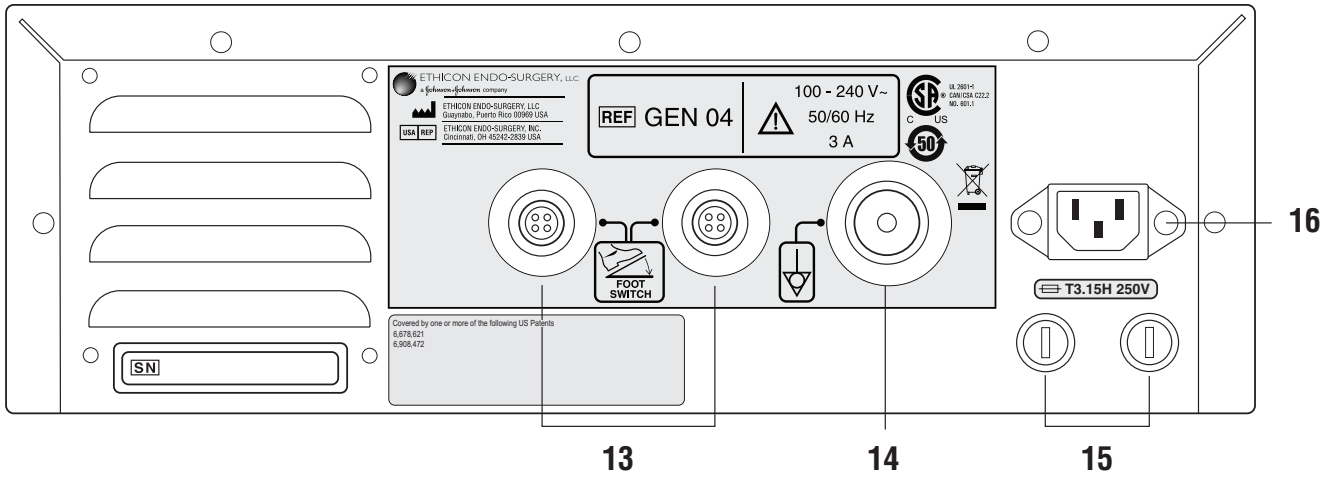


Fig. 5-2 Back Panel

13	**FOOT SWITCH RECEPTACLES**	Identical receptacles allow connection of up to two foot switch assemblies for user convenience. If only one foot switch is used, connect to either receptacle.
14	**POTENTIAL EQUALIZATION TERMINAL**	This terminal provides a means for connection to a Potential Equalization Conductor.
15	**FUSES**	Refer to the Replacement Parts drawings in the back of this manual for additional fuse locations and fuse type.
16	**POWER CORD RECEPTACLE**	This receptacle is used to attach the power cord to the generator. For power cord requirements, refer to Chapter 14 – System Specifications.
	AUDIBLE SIGNALS	The generator delivers audible tones to signal activation, test, and alarm states. The user may choose from three activation tone pitches. Refer to Chapter 15 – Adjustments for tone selection information. Upon power-up, the system defaults to the last tone chosen (the mid-pitch tone is factory-set).

Screen Descriptions

Power-Up Screen
Below is an **example** of the Software Version displayed during power-up.

Fig. 5-3 Power-Up Screen

Tone Selection Screen
Refer to Chapter 15 – Adjustments for descriptions of the Tone Selection Screens.

User-Initiated and Pre-Activation Test Screens
The generator will cycle between the following two screens, displaying each screen briefly, for the duration of the time that the system is in the User-Initiated Test state and Pre-Activation Test state. Refer to Chapter 7 – Safety and Function Testing for details.

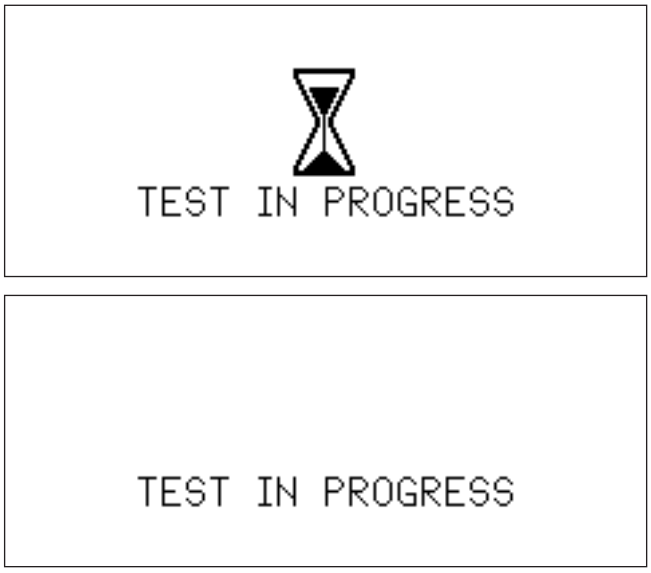


Fig. 5-4 Test in Progress Screens

Standby, Ready and Run Screens
The Standby, Ready, and Run screen appearances depend on the mode in which the system is running. In Normal mode, the Standby, Ready, and Run screens are the same and indicate the MAX power level of 5 on the right, and the user selected MIN power level on the left (1 to 5). In Developer/Biomed mode, the Standby screen indicates the user selected MIN power level on the left, and a subset of system parameters on the right. In Developer/Biomed mode, the Ready screen displays the user selected MIN Power level on the left (1 to 5) and the system run time parameters on the right. Developer/Biomed Run screen is identical to the Developer/Biomed Ready screen.

The following are all possible screens for the Standby, Ready, and Run states in Normal mode. The number on the left indicates the power level for MIN activation (1 to 5), and the number on the right is the power level for MAX activation.

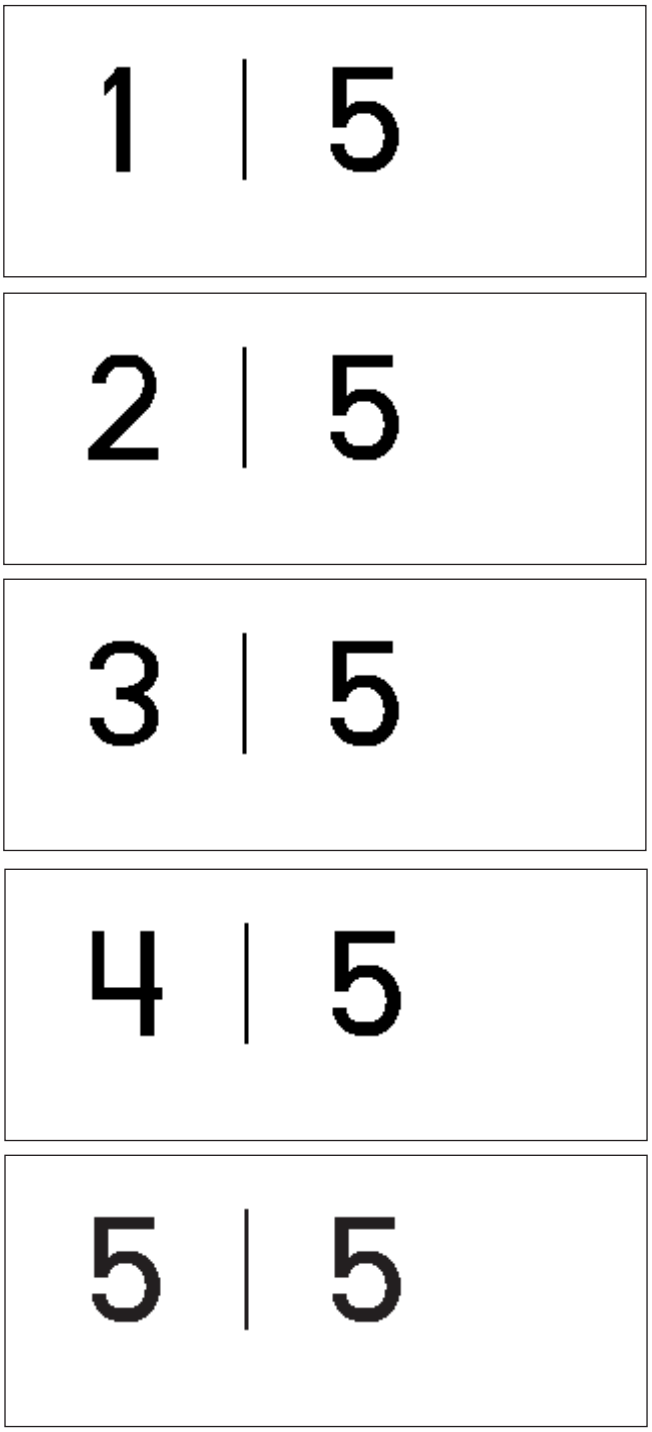


Fig. 5-5 Standby, Ready and Run Screens in Normal Mode

Error Screens

Refer to Chapter 9 – High-Level System Troubleshooting for examples of each of these screens.

System Operation

For an understanding of system operation, refer to the HARMONIC Generator 300 System User Manual for instructions and specifications for use of the HARMONIC Generator 300 System, Foot Switch, and Cart. Refer to package inserts provided separately for information about the Hand Piece, Hand Switching Adaptor, Adaptors, Test Tip and Instruments prior to using the system. This manual is not a reference to surgical techniques.

After completing system setup, the system may be operated.

1 Place the generator in Ready mode by depressing the STANDBY button.

Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.

2 System check and activation:

Each time the generator is activated after exiting Standby, hold the instrument in the air (if coagulating shears are used, open the clamp arm) and depress the MIN or MAX power level on the foot switch or hand switching adaptor. "TEST IN PROGRESS" will appear on the graphic display and a rapid two-tone pulse will sound while the test is occurring. During this five-second period, a system check is being performed.

• If the system is operating properly, the activation tone corresponding to the power level activated will be heard when the check is complete. Stop activation, position the instrument on tissue, and resume activation.
• If the system is not operating properly, an error code will appear (refer to Chapter 9 – High-Level System Troubleshooting or the Troubleshooting Guide located on top of the generator unit).

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects during the system check. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect during the system check.

Note: The foot switch or hand switch must be depressed until the system check is complete. If the switch is released prematurely, the check will reinitiate at the next activation.

Note: The HAND ACTIVATION button on the generator control panel must be illuminated for the hand switch to be active. To deactivate the hand switch, depress the HAND ACTIVATION button (if the HAND ACTIVATION button is not illuminated, hand switch will be inactive).

Note: If the hand switch will not turn off during operation, depress the button corresponding to the power level opposite that being activated to turn it off - an alarm will sound. Press the HAND ACTIVATION button to disable the hand switching adaptor. Place the generator in Standby, and replace the hand switch; or, continue using the foot switch after deactivating the hand switch.

3 If the system senses a generator, hand piece, or instrument fault during use, an audible alarm (tone with long pulses) will sound and a visual alarm indicator will appear on the control panel. (Refer to Chapter 9 – High-Level System Troubleshooting or the Troubleshooting Guide on top of the generator unit to resolve the problem.)

Warning: Place the generator in Standby before removing or replacing an instrument, hand switching adaptor or hand piece or when the system is not in use.

System Shutdown

1. Turn the generator power switch off and remove power cord from outlet.
2. Disconnect the hand piece, instrument, and adaptor or hand switching adaptor (if used) and process them as indicated in their respective package inserts.
3. Clean the generator and cart and disinfect the foot switch(es) following hospital protocol. Refer to the HARMONIC Generator 300 System User Manual for detailed Cleaning and Disinfection instructions.
4. Store foot switch(es) on the cart shelves provided. Each shelf will hold one foot switch.
5. Wrap foot switch cable(s) and the power cord on the cart's back handle for storage.

Generator and Cart Cleaning

Clean generator and cart following hospital protocol. Before cleaning, turn the generator main power off and unplug the power cord from the grounded electrical outlet.

Warning: Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.

Refer to the HARMONIC Generator 300 System User Manual for detailed Cleaning and Disinfection instructions.

Foot Switch Cleaning

The foot switch and cable should be cleaned after each use.

Refer to the HARMONIC Generator 300 System User Manual for detailed Cleaning and Disinfection instructions.

Disinfection (Generator, Footswitch and Cart)

Surface disinfection of the Generator, Foot Switch and Cart should follow the cleaning process. Particular attention to the disinfectant manufacturer's recommendations must be followed for equipment that is knowingly and/or visibly contaminated with blood or bodily fluid. The foot switch can be immersed in the disinfectant solution.

Note: Keep the footswitch cable connector that connects to the generator dry at all times.

Refer to the HARMONIC Generator 300 System User Manual for detailed Cleaning and Disinfection instructions.

Test the hand piece, generator, and foot switch for safety and function according to hospital protocol. Refer to individual package inserts for safety and function testing for other multi-patient use components.

Safety Test

Generator: A qualified hospital technician should perform a leakage current test.

Foot Switch: Examine the foot pedals, cable connectors, and cable for cracks or other damage and replace if damaged.

Other Components: Examine the components by following the instructions in their individual package inserts.

Function Test

1 Attach the hand piece to the generator as described in Chapter 4 – System Setup, then attach the test tip rather than an instrument.

2 Verify that the orange STANDBY indicator is illuminated.

3 Push the STANDBY button to leave Standby mode and enter Ready mode.

Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.

4 Verify that the green READY indicator is illuminated.

5 Verify that MIN Power Level 3 and MAX Power Level 5 are displayed.

6 Push the Increase and Decrease Power Level button up and down to confirm the MIN Power Level changes from 1 to 5.

7 Turn the generator off. Wait five seconds, then turn the generator back on. Wait ten seconds, then confirm MIN Power Level 3 and MAX Power Level 5 are displayed. Confirm the generator is not being activated unexpectedly.

8 Press the TEST button to perform a User-Initiated Test. The system will run a series of tests to ensure the generator and hand piece are in proper working condition.

9 Place the generator in Ready mode by depressing the STANDBY button. Hold the hand piece so that the distal portion is in the air and step on the MAX foot switch pedal (before activation begins, a five-second system check will be performed – "TEST IN PROGRESS" will appear on the display). After the test is completed, verify that the MAX Power Level indicator on the control panel flashes and that the MAX activation tone is heard.

Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

10 Hold the hand piece so that the distal portion is in air and step on the MIN foot switch pedal. Verify that the MIN Power Level indicator on the control panel flashes and that the MIN activation tone is heard.

Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

Procedure for Checking the output of GEN300 Generators

1 Perform the functional test sequence of steps contained in the service manual, Chapter 7 – Safety and Function Testing (page 23).

2 Then check the generator's current output:

a. Power the generator off. Wait 10 seconds.

b. Power the generator on while firmly pressing both "**Standby**" and "**Min Power-down**" buttons simultaneously. Continuously press the two buttons until page number 1 of the BME display mode is visible and only the Standby indicator is lit.

Note: A Generator "**Error Code #1**" will result if the two buttons are not continuously pressed as described and the generator will have to be powered down and back up again.

c. Connect a known good HP054 Hand Piece to the generator.

Note: Make sure the hand piece is not hot (i.e., at room temperature).

d. Using the torque wrench for the hand piece, attach the test tip to the hand piece.

e. Use the up and down arrows to scroll to page 2.

f. **Record** the current set point value for the hand piece listed on page 2.

Expected Output Current = _____

g. Press the "**Standby**" key to enter Ready state.

h. Activate at level 5 by pressing the max foot switch pedal or max switch on the hand switching adapter while keeping the test tip in air.

i. Allow the pre-run test to complete. Terminate activation after regular max activation beeps are audible.

j. **Record** the current on the display while continuing to activate at level 5.

Actual Current Output = _____

k. Note: The current read should be within **+/- 1%** of the current recorded on page 2 of the standby screen's display.
If further confirmation of output is desired, remove the box cover and measure the current in step f with a true RMS Digital Volt Meter with a bandwidth of at least 300Khz .
Make the voltage measurement across the series combination of R233 & R234.

Note: For ease of testing and best accuracy, clip one test lead on the leg of R229 closest to R233 and hold the other test lead on the leg of R234 that is furthest away from R229.

Note: Since the resistance value of the series combination of R233 & R234 is 1ohm, the voltage read in mV RMS is equal to the current in mA RMS.

3 If the GEN300 passes the above steps, then generator current output is functioning properly.

The HARMONIC Generator 300 System supports a series of audible and visual alarms, as well as error codes displayed on the unit's LCD, to help in the identification and troubleshooting of problems down to the assembly level (i.e. generator, hand piece, foot switch, hand switching adaptor, etc.). These guides are meant as an adjunct to, but not a substitute for, clinical judgment and observations.

If the problem cannot be resolved using the corrective actions below, contact the Ethicon Endo-Surgery Customer Response Center at 1-800-USE-ENDO for assistance. Please have the model number, serial number from the rear panel of the generator, and a detailed description of the problem. The description of the problem should include power settings, accessories used, procedure being performed, and software revision of the unit.

Warning: Electric shock hazard. Always unplug the generator from the wall outlet prior to opening the cover for servicing.

Warning: After removing the cover, inspect the internal components for obvious damage or foreign debris. Never power ON a damaged unit.

Audible Indicators and Alarms

Tone	Possible Cause and Corrective Action
No tone during power-up.	Generator failure. Contact service personnel.
No tone when system is activated.	Confirm that the foot switch is fully connected (if hand switching adaptor is not being used). Confirm foot switch is not faulty. If hand switching adaptor is used, confirm it is connected and not faulty. Confirm that hand activation is enabled if the hand switching adaptor is being used.
Activation (brief pulses)	System is being activated or is in Test mode. System is operating properly. MIN and MAX power have unique tones.
Alert (three-tone sequence)	Activation is attempted while generator is in Standby mode. Push the STANDBY button to return the generator to Ready mode. Two or more foot or hand activation switches are recognized by the generator as being activated simultaneously. Release all activation switches and reactivate using only one switch.
Constant tone	**1**. Instrument is in contact with too much tissue. Reduce the amount of tissue in contact with the instrument. If tone persists, carefully remove any tissue that has collected in the distal end of the instrument shaft. **2**. Hand piece and/or blade fault. Press TEST to identify source of fault.

Prolonged solid tone during activation (exceeds 10 seconds)	Hand piece and/or blade fault. Press TEST to identify source of fault.
Alarm (two-tone sequence)	A component or system problem has occurred. Refer to the Error Codes section in this chapter or the Troubleshooting Guide. Note: This alarm will activate for three seconds, then will silence itself for 30 seconds. This cycle will continue until the error is resolved or the main power switch is turned off.

Error Codes and Displays in Normal Operating Mode

The generator will recognize specific faults in five areas: generator, hand piece, instrument, foot switch or hand switch. When a fault is identified, an alarm will sound, the alarm indicator will appear on the generator control panel, and the source of the problem will appear on the graphic display (the power levels will not be displayed).

If an error code is displayed, follow the procedures outlined below (or in the Troubleshooting Guide on the top of the generator unit) to resolve the problem.

Note: For each error code, the generator will cycle between each of the two screens shown in the examples below, with the faulty component flashing.

Error Code 1: Generator

Error Code 1 indicates either there is a functional problem with the generator or the front panel button(s) were activated during power-up sequence.
Cycle the power OFF, then ON. If error persists, power off system and contact service.

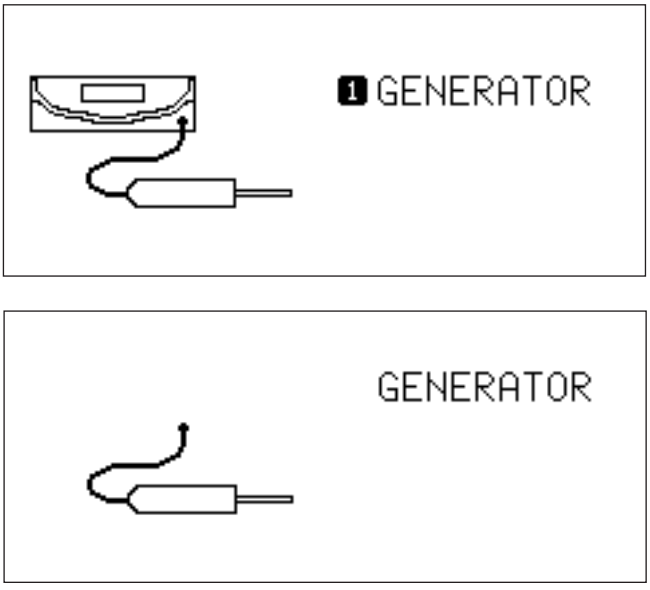


Fig. 9-1 Generator Failure Screens

Error Code 2: Generator Temperature

Error Code 2 indicates that the generator is overheating.

1. Power off system. Remove any obstructions blocking the air vents on the generator's bottom and back panels. If there is no apparent obstruction or external heat source, contact service.
2. Power on the system and wait for up to 30 minutes for generator error to clear.
3. If error code persists, contact service.

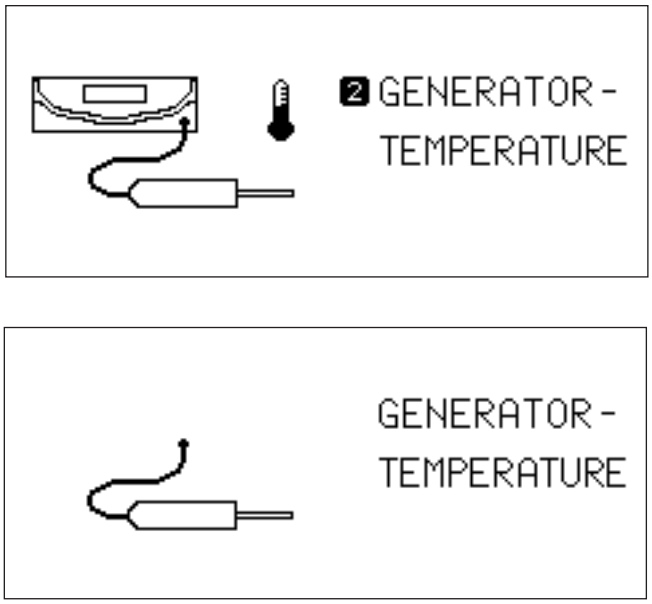


Fig. 9-2 Generator Over-Temperature Error Screens

Error Code 3: Hand Piece

Error Code 3 indicates a problem with the hand piece.

1 Confirm that the hand piece connector is fully inserted and properly oriented – white dot on hand piece is aligned with white dot on front panel. If the error code does not clear within three seconds after the hand piece is properly connected, press TEST.

2 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

3 If the error persists, install a test tip to isolate the problem. Press TEST button.
- If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
- If no error occurs with test tip attached, replace instrument.

4 Press STANDBY to return to Ready mode. Activate system.

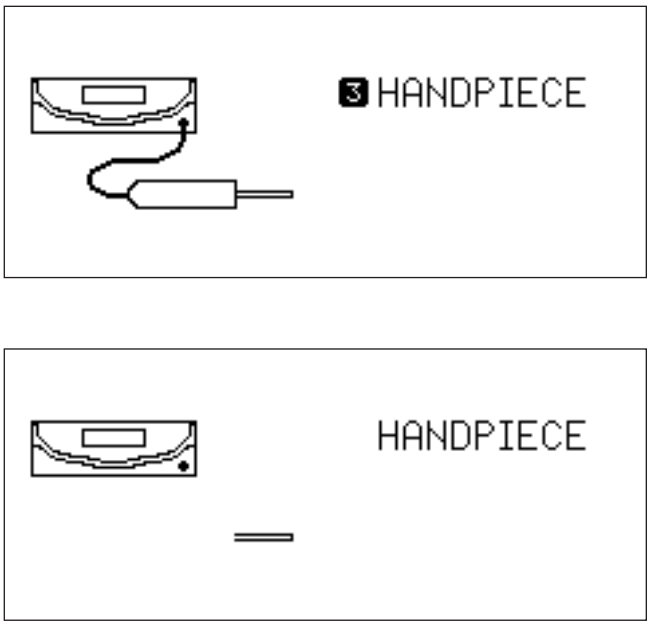


Fig. 9-3 Hand Piece Generic Error Screens

Error Code 4: Hand Piece Temperature

Error Code 4 indicates that the hand piece has exceeded its specified operating temperature. For immediate recovery, use another hand piece; or, follow the steps below to determine the cause of the error condition and alternate recovery methods.

The following are possible causes of an increase in hand piece temperature. To correct, complete the appropriate steps below and ***allow the hand piece to cool before resuming operation***.

1 The hand piece is still warm from recent steam sterilization. Allow the hand piece to cool at room temperature for at least 45 minutes or, for rapid cooling, soak it in room-temperature sterile water for 5 minutes before resuming operation.

Note: The hand switching adaptor (HSA07) should not be submerged for rapid cooling purposes. This may render the hand switching adaptor inoperable for an extended period of time. After steam sterilization, allow the hand switching adaptor to air cool at least 15 minutes prior to use.

2 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

3 If the error persists, install a test tip to isolate the problem. Press TEST button.

- If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
- If no error occurs with test tip attached, replace instrument.

4 Press STANDBY to return to Ready mode. Activate system.

5 If the hand piece does not show evidence of overheating and troubleshooting steps 1-4 above do not appear to resolve the problem, perform the following:

a. Leave the hand piece at room temperature for 24 hours or more.
b. Remove any test tip or instrument from the hand piece.
c. With the generator turned off, plug the hand piece into any Generator 300.
d. Power up the generator in Biomed mode.
- Press and hold down the STANDBY button and down arrow key.
- Wait for a steady display – approximately 10 seconds.
- If a "Generator" error occurs, then one of the buttons was not properly held down. If this happens, repeat the power up procedure in Biomed mode.

e. Record the "XDUCER CAPACITANCE" value.
- Press the STANDBY button, if necessary, until it illuminates.
- Use the increase/decrease arrow keys to get to "Page 2 of 21".
- Record the number opposite "XDUCER CAPACITANCE".
- Press the STANDBY button until the Standby light turns off.
- Leave the hand piece plugged into the generator. Do not remove hand piece during entire procedure. Do not activate the MIN or MAX activation buttons on the foot switch or hand switch if either is attached.
- After a period of time that exceeds 30 or more minutes, press the STANDBY button until the STANDBY icon is illuminated.
- Again, read the "XDUCER CAPACITANCE" on Page 2 of 21.
- If the number has changed, the update was successful.
- If the number has not changed, then this update attempt did not succeed. Power down the generator and repeat Step 5.

Note: As the hand piece ages, the generator performs measurements and updates a key hand piece parameter. This function is performed when the internal temperature of the hand piece is stable at room temperature. Certain usage patterns may prevent this update from occurring and subsequently make the hand piece diagnostics more sensitive to temperature. The steps above will cause an update of the hand piece parameter and return the system to designed sensitivity.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electrosurgical generator is being activated in the room. Interference from the electrosurgical generator may affect test results.

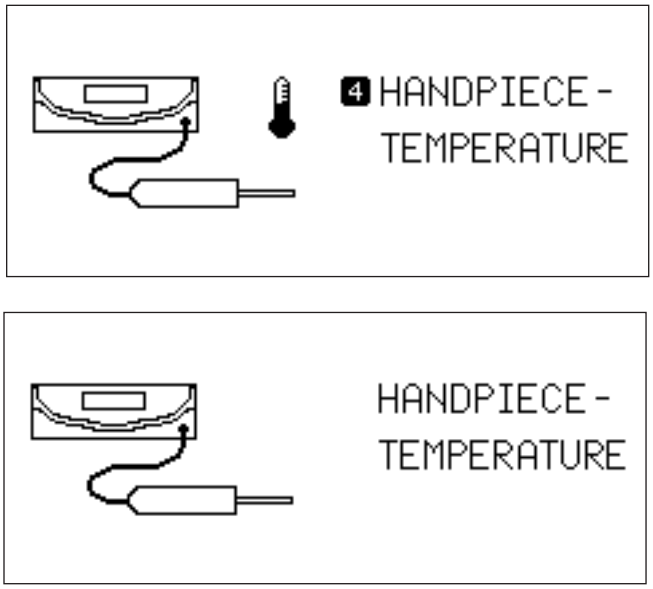


Fig. 9-4 Hand Piece Over-Temperature Error Screens

Error Code 5: Instrument

Error Code 5 indicates a problem with the instrument.

- The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

  Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

2 If the error persists, install a test tip to isolate the problem. Press TEST button.

- If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
- If no error occurs with test tip attached, replace instrument.

3 Press STANDBY to return to Ready mode. Activate system.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient, or other interference before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electrosurgical generator is being activated in the room. Interference from the electrosurgical generator may affect test results.

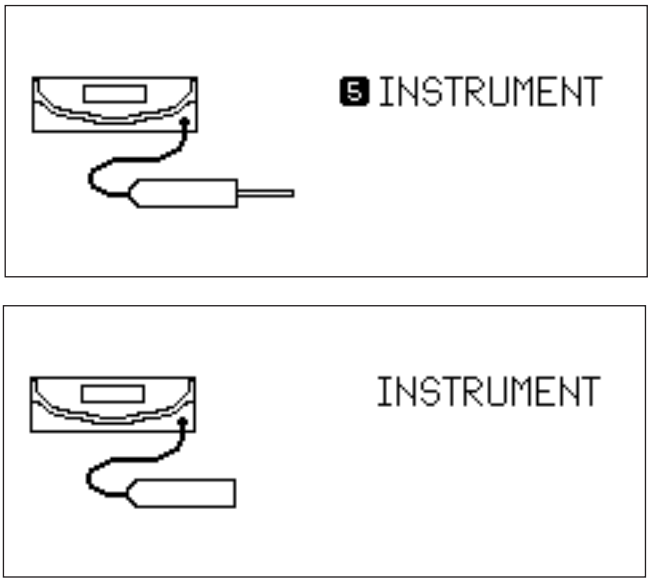


Fig. 9-5 Instrument Generic Error Screens

Error Code 6: Foot Switch

Error Code 6 indicates a foot switch pedal is stuck in the ON position. Confirm generator receptacle, foot switch receptacles and cable connectors are clean and dry or replace the foot switch.

Note: If the error persists, replace foot switch.

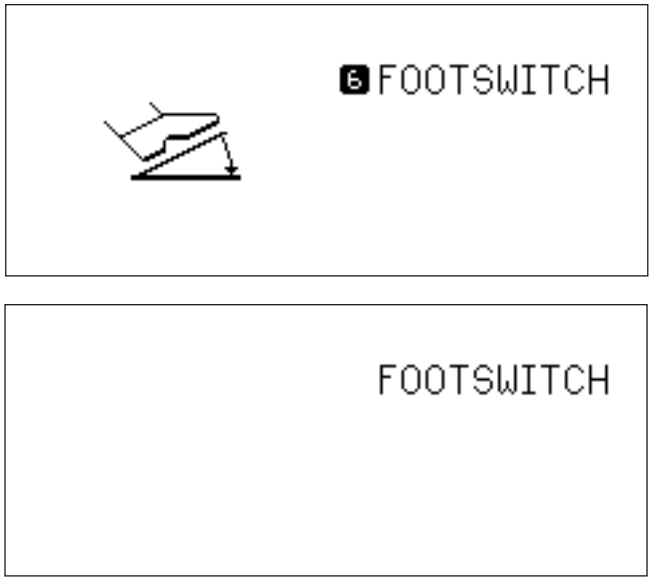


Fig. 9-6 Foot Switch Assembly Error Screens

Error Code 7: Hand Switch

Error Code 7 indicates the hand switch is stuck in the ON position. Confirm contacts in the distal end of hand piece and in the proximal end of the hand switching adaptor are dry or replace the hand switching adaptor.

Note: If the error persists, replace hand switch.

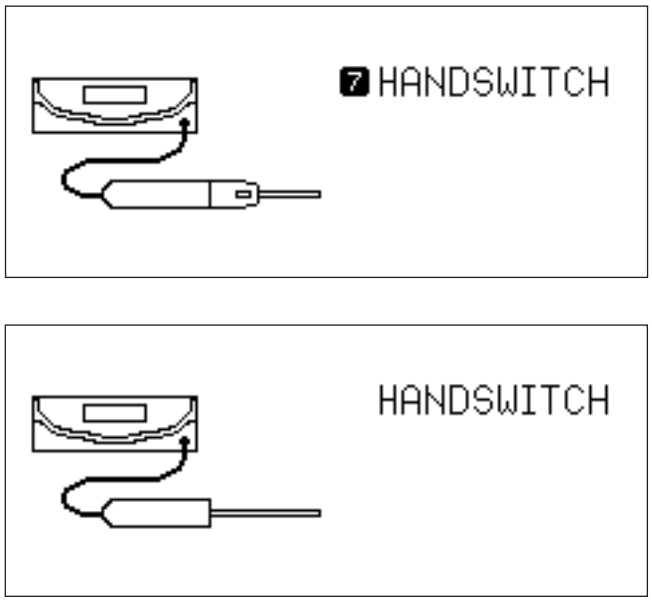


Fig. 9-7 Hand Activation Assembly Error Screens

Procedure for checkout/screening of HP054 Hand Pieces

Note: You must use a calibrated HARMONIC GEN 300 for testing hand pieces.

1 Perform the functional test sequence of steps contained in the service manual, Chapter 7 – Safety and Function Testing (page 23).

2 Power the generator on while firmly pressing both "**Standby**" and "**Min Power-down**" buttons simultaneously. Continuously press the two buttons until page number 1 of the BME display mode is visible and only the Standby indicator is lit. A Generator "**Error Code #1**" will result if the two buttons are not continuously pressed as described and the generator will have to be powered down and back up again. Check hand piece for loose stud. If the stud is loose, the hand piece is defective and subsequent testing is not required.

Note: Ensure that the area around the base of the stud is clean.

3 Using the torque wrench for the hand piece, attach the test tip to the hand piece.

Note: Make sure the test tip is not visibly damaged (i.e., dinged or otherwise).

5 Plug the hand piece into the generator.

6 Perform a User Initiated Test by pressing the "**TEST**" button. If an error is detected, the hand piece is defective and subsequent testing is not required.

7 Perform the following while the generator is in Standby:

a. On BME display pg 1 –

i. **Record the value of "HP Procedures:" (the estimated number of procedures the hand piece has been used in)**.

Note: The average hand piece life is 95 procedures, although we have seen hand pieces go beyond the average life. If the value of HP procedures is getting close to 65435, then the hand piece is close to 95 procedures.

Approx. Number of procedures = _____

b. On BME display pg 8 –

i. **Record the value of "PM"** – PM stands for Phase Margin, and a good Hand Piece with a test tip should be between 170 and 247.

Note: As the Hand Piece ages, the PM decreases; therefore, if the PM is close to 170 or below, and some of the other parameters are close to their limits, the Hand Piece is getting closer to its "end of useful life." Using a Hand Piece that operates near its end of useful life may result in one or more of the following:

- generator error codes
- Hand Piece over heating
- generator lock outs

PM Value = _____

ii. **Record the value of |Zr|** - |Zr| is the value of the hand piece impedance as measured by the generator, and for a good hand piece and test tip, this value should be between 15 and 46 Ohms.

Note: As the hand piece ages, the |Zr| value increases; therefore, if the |Zr| value is above 40 Ohms the hand piece is approaching its "end of useful life." Using a hand piece that operates near its end of useful life may result in one or more of the following:

- generator error codes
- hand piece over heating
- generator lock outs

|Zr| Value = _____

8 Press the standby button to place generator in "**Ready State.**"

9 Activate at level 5 until the pre-run test is complete.

10 Stop activation after pre-run test completes.

11 Reactivate at level 5.

12 **Record** the value of "**impedance**" on the display while continuing to activating at level 5.

Impedance = _____

Note: As the hand piece ages, the impedance value increases; therefore, if the impedance value is above 40 Ohms the hand piece is approaching its "end of useful life." Using a hand piece that operates near its end of useful life may result in one or more of the following:

- generator error codes
- hand piece over heating
- generator lock outs

If you need further assistance, please contact the Ethicon Endo-Surgery Customer Support Center at 1-800-USE-ENDO (800-873-3636), Option 2.

Error Code Display

Generators with software version 1.09 and previous contain an error code display as a troubleshooting aid for Biomedical Engineers or technicians. The error codes can be accessed by pressing the Standby and "MIN Power-down" buttons simultaneously until BME nide appears.

Error Codes

Hex error code	Message on the LCD	Message hidden in code	Error Group	
09	FS1 SHORTED,\nFS1 PRESENT	FS1_SHORTED_PRESENT_FAULT	6	Foot Switch
0A	FS2 SHORTED, \nFS2 PRESENT	FS2_SHORTED_PRESENT_FAULT	6	Foot Switch
0B	FS1 SHORTED, \nFS1 NOT PRESENT	FS1_SHORTED_NOT_PRESENT_FAULT	6	Foot Switch
0C	FS2 SHORTED, \nFS2 NOT PRESENT	FS2_SHORTED_NOT_PRESENT_FAULT	6	Foot Switch
10	FS2 SHORTED, \nFS2 PRESENT	FS2_SHORTED_PRESENT_FAULT	6	Foot Switch
11	HP ACTIVATION \nSWITCH SHORTED	HP_ACTIVATION_SHORTED_FAULT	7	Hand switch
16	FET SOA FAULT \n	FET_SOA_FAULT	5	Instrument
17	GUNKED BLADE \n#329	HP_GUNKED_BLADE_329	5	Instrument
18	MULTI-LEVEL \nGUNK BLADE #279	HP_MULTI_LEVEL_GUNK_BLADE_264	5	Instrument
19	HP WITH LOOSE \nBLADE/STUD #257	HP_LOOSE_BLADE_STUD_FAULT_257	5	Instrument
1A	HP TESTED W/O \nBLADE #258	HP_TEST_WO_BLADE_FAULT_258	5	Instrument
1B	HP WITH BAD \nBLADE #262	HP_W_BAD_BLADE_262	5	Instrument
1C	PRE RUN \nATTACHMENT #291	HP_PRE_RUN_ATTACHMENT_291	5	Instrument
1D	PRE-RUN BROKEN \nBLADE #284	HP_PRERUN_BROKEN_BLADE_284	5	Instrument
1E	RUN BROKEN \nBLADE #320	HP_RUN_BROKEN_BLADE_FAULT_320	5	Instrument
1F	LUMPED PARMS \nGENERIC #283	LUMPED_PARMS_FAULT_283	5	Instrument
20	MULTI-LEVEL \nGENERIC #281	MULTI_LEVEL_FAULT_281	5	Instrument
21	no error code defined	GENERIC_AT_RES_BLADE_FAULT	5	Instrument
22	GENERIC PRE-RUN\nFAULT	GENERIC_PRERUN_FAULT	5	Instrument
2E	HP DATA FAULT \n	HP_DATA_FAULT	3	Handpiece
2F	HP NOT PRESENT \nFAULT	HP_NOT_PRESENT_FAULT	3	Handpiece
38	PRESENT NOT HP \nFAULT	PRESENT_NOT_HP_FAULT	3	Handpiece
39	NON EES HP \nFAULT	NON_EES_HP_FAULT	3	Handpiece
3A	UNAUTHORIZED HP\nFAULT	UNAUTHORIZED_HP_FAULT	3	Handpiece
3B	INVALID HP PARM\nFAULT	INVALID_HP_PARM_FAULT	3	Handpiece
3C	HP PRESENT,FETS\nNOT BIASED	HP_PRESENT_NO_FET_BIAS_FAULT	3	Handpiece
3D	OFF-RES C0 \nMEAS. FAULT	HP_OFFRES_C0_MEASUREMENT_FAULT	3	Handpiece
4C	PRE RUN TRANS- \nVERSAL #324	HP_PRE_RUN_TRANSVERSAL_324	3	Handpiece
4D	HIGH C0 RATE OF\nCHANGE #293	HP_HIGH_C0_RATE_OF_CHANGE_293	3	Handpiece
4E	HP END OF LIFE \n#292	HP_END_OF_LIFE_292	3	Handpiece
4F	BAD HP WITH \nTEST TIP #258	BAD_HP_W_TEST_TIP_FAULT_258	3	Handpiece
50	UNSTABLE OUTPUT\nHP OPEN FAULT	UNSTABLE_OUTPUT_FAULT	3	Handpiece
51	HP SHORTED \nFAULT #253	HP_SHORTED_FAULT_253	3	Handpiece
52	HP OPEN FAULT \n #254	HP_OPEN_FAULT_254	3	Handpiece
53	RUN STATE HP \nSHORTED	RUN_HP_SHORTED_FAULT	3	Handpiece
65	HANDPIECE HIGH \nTEMP (AT-RES)	HP_OVER_TEMP_RES_FAULT	4	HP Over temp
66	HANDPIECE HIGH \nTEMP #319	HP_OVER_TEMP_319	4	HP Over temp
6F	HEATSINK HIGH \nTEMP FAULT	HS_OVERTEMP_FAULT	2	Gen Over temp
70	PCB OVERTEMP \nFAULT	PCB_OVERTEMP_FAULT	2	Gen Over temp
97	A/D CONVERTER \nFAILURE	ADC_FAILURE	1	generator
98	FET BIAS \nFAILURE	FET_BIAS_FAILURE	1	generator
99	HANDPIECE ID \nFAILURE	HANDPIECE_ID_FAILURE	1	generator
9A	SCI FAILURE \n	SCI_FAILURE	1	generator
9B	BEZEL SWITCH \nSTUCK FAILURE	BEZEL_SWITCH_STUCK_FAILURE	1	generator
9C	EEPROM FAILURE \n	EE_FAILURE	1	generator
9D	EEPROM TIMEOUT \nFAILURE	EE_TIMEOUT_FAILURE	1	generator
9E	AUDIO TIMEOUT \nFAILURE	AUD_TIMEOUT_FAILURE	1	generator
9F	WATCHDOG \nFAILURE	WATCHDOG_FAILURE	1	generator
A0	NMI ISR \nFAILURE	NMI_ISR_FAILURE	1	generator
A1	PHANTOM ISR \nFAILURE	PHANTOM_ISR_FAILURE	1	generator
A2	ROM CRC FAILURE\n	ROM_CRC_FAILURE	1	generator
A3	DATA MEMORY \nFAILURE	DATA_MEM_FAILURE	1	generator
A4	DSP CORE \nFAILURE	DSP_CORE_FAILURE	1	generator
A5	DISPLAY FAILURE\n	DISPLAY_FAILURE	1	generator
A6	POWER SUPPLY \nFAILURE	POWER_SUPPLY_FAILURE	1	generator
A7	SOFTWARE INT \nFAILURE	SOFTWARE_INT_FAILURE	1	generator
A8	MITIGATION \nFAILURE	MITIGATION_FAILURE	1	generator
A9	STR VAL OUT OF \nBOUNDS FAILURE	STR_VAL_OUT_OF_BOUNDS_FAILURE	1	generator
AA	UNKNOWN FAILURE\n	UNKNOWN_FAILURE	1	generator
AB	OVERCURRENT \nFAILURE	OVERCURRENT_FAILURE	1	generator
AC	ILLEGAL ADDRESS\nFAILURE	ILLEGAL_ADDR_FAILURE	1	generator
AD	SPI FAILURE \n	SPI_FAILURE	1	generator
AE	AUDIO FAILURE \n	AUDIO_FAILURE	1	generator
AF	STACK \nFAILURE	STACK_FAILURE	1	generator
B0	VOLTAGE \nMITIGATION	VLVL_MITIGATION_FAILURE	1	generator

Software Version 1.09 Enhanced Display Functionality

Software version 1.09 adds some enhancements to the displayed information over previous versions of software (Fig.11-1):

- Momentarily Displays Hand Piece usage during Power-up (normal mode).
- Provides an enhanced Generator / Hand Piece errors display mode:

  How to enter: Power up generator and firmly press the Standby and "MIN Power-up" buttons simultaneously until enhanced error mode display appears.

  The error code information related to specific technical issues is identical to the Hex code display, but with these added enhancements for each error code:

  - Error Code Time Stamp
  - Error Code Text Description
  - If hand piece related, the Lot Number and Transducer Number of the hand piece that was being used is displayed.

  Caution: Make sure to press BOTH buttons simultaneously, otherwise Generator "Error code #1" will show up (which will require to power the generator down and then back.
- Errors stored in generator memory will be displayed, most recent error first.
- Pressing the "hand-activation" button while in enhanced error display mode will cause the errors stored in the hand piece memory to be displayed (hand piece must be connector to generator).

Estimating Hand Piece Usage

Power-up state
(after dark display)

Fig. 11-1 Software Version 1.09 Display

Generator Error Log Record

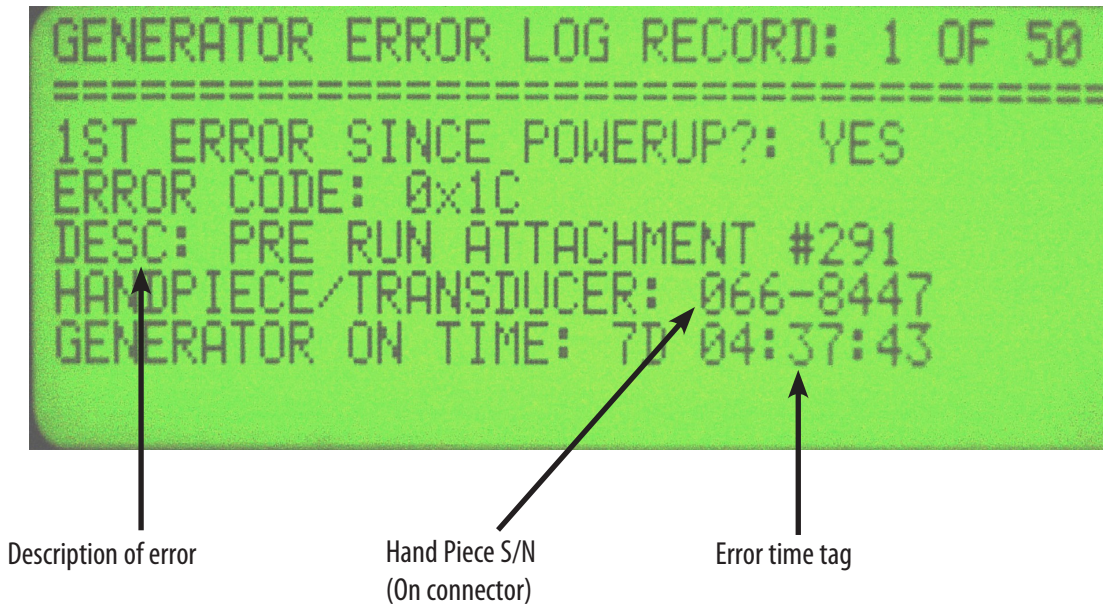


Fig. 11-2 Software Version 1.09 Display (Cont.)

Hand Piece Error Log Record

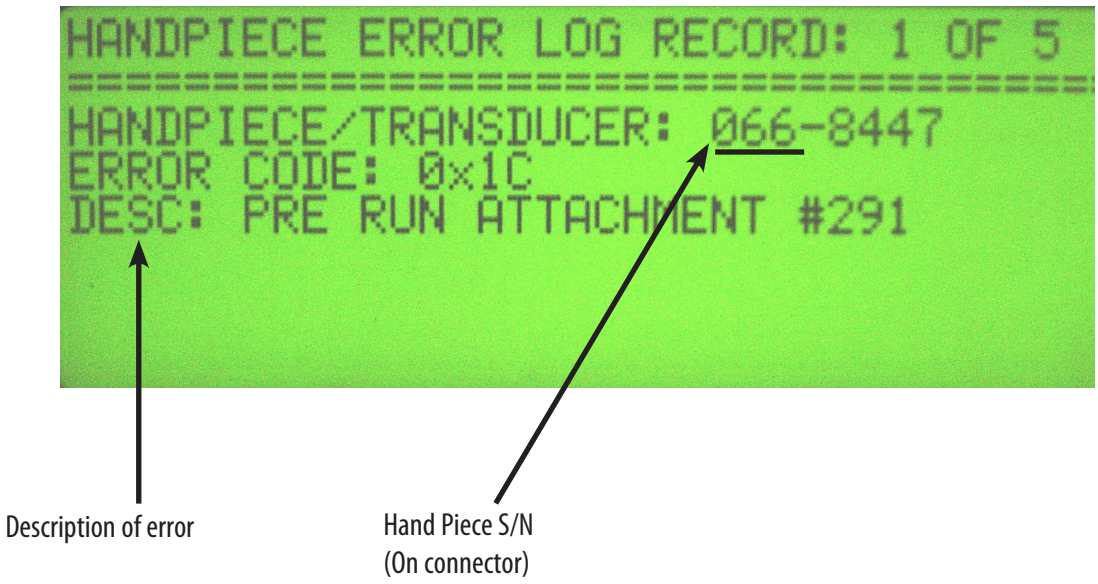


Fig. 11-3 Software Version 1.09 Display (Cont.)

The procedures described on the following pages require the generator to be powered up while the cover is removed. Caution should be taken to avoid making direct contact with any of the internal components while the unit is powered up.

Warning: The AC mains voltage presents a shock hazard and is accessible when the generator cover is removed. Caution must be used near internal system components, which attach directly to the AC mains such as the power entry module, mains fuses, power switch, and open-frame 48V power supply.

Test Equipment and Tools

High-level troubleshooting of the HARMONIC Generator requires the following tools:

- Digital Multi-meter
- Phillips screwdriver

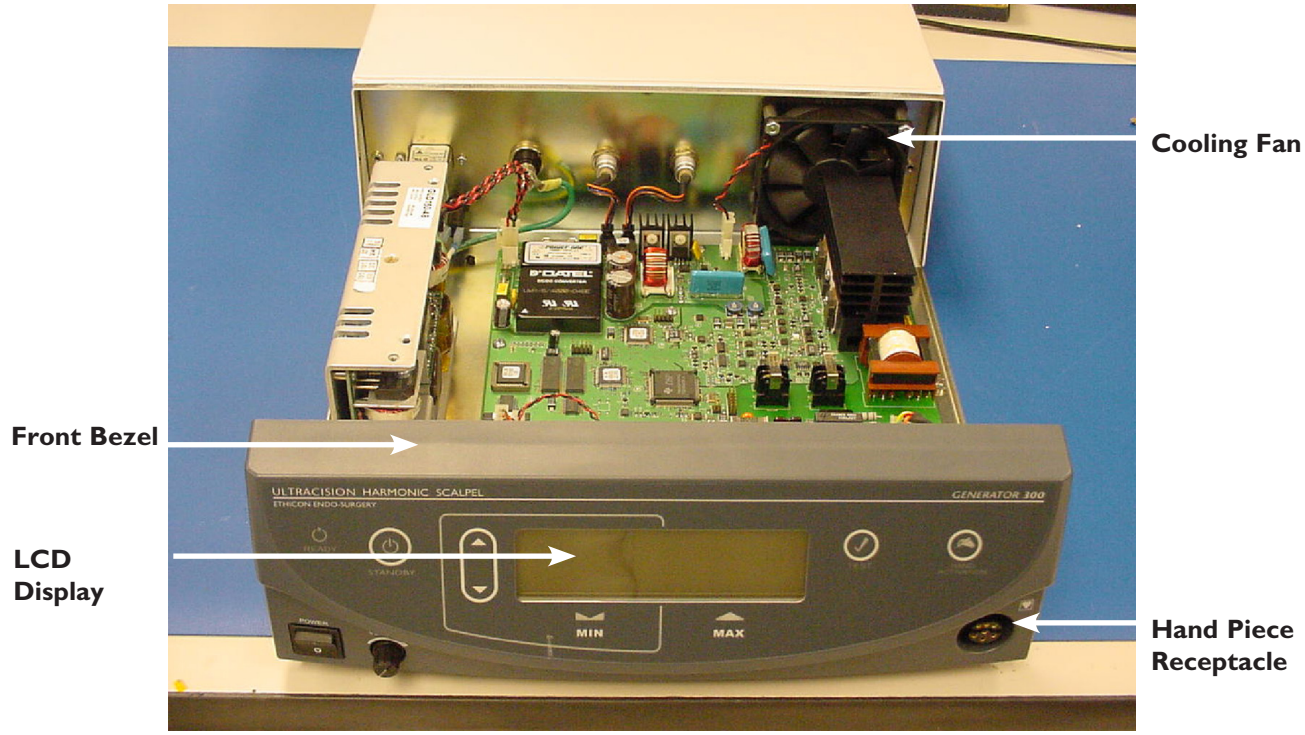


Fig. 12-1 Front Bezel Components and Cooling Fan

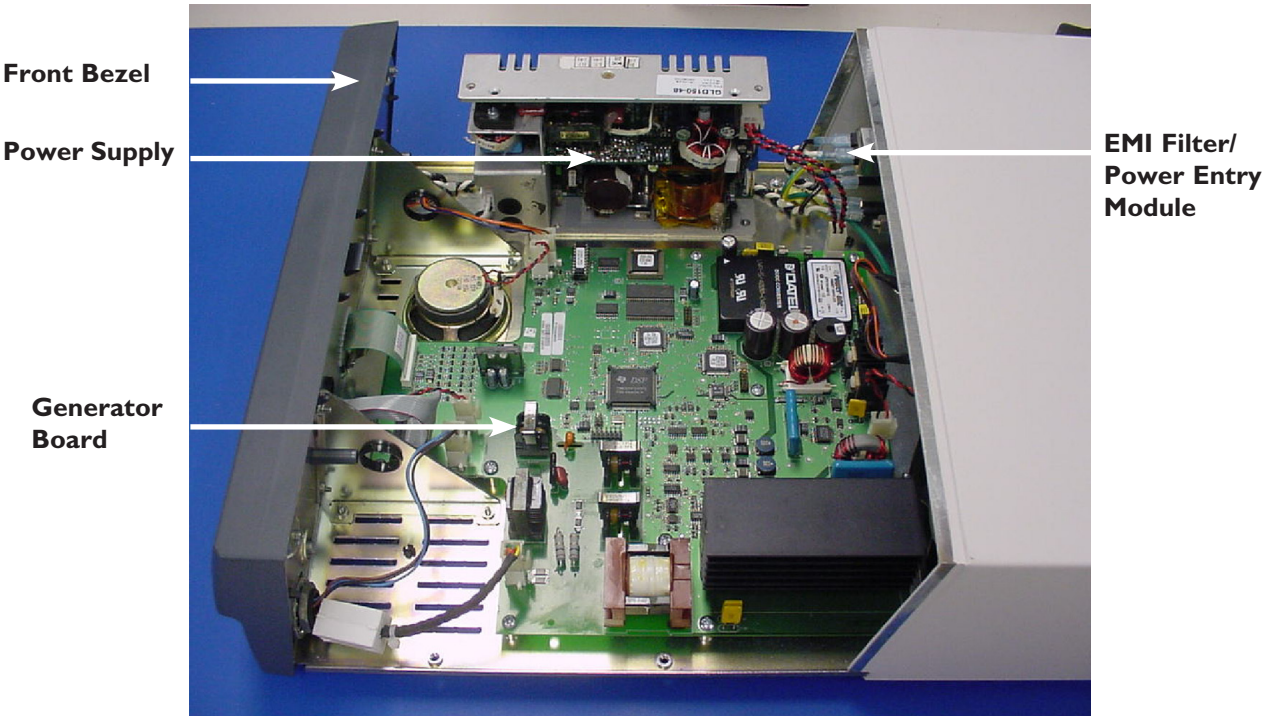


Fig. 12-2 Front Bezel, Power Supply, Generator Board, and EMI Filter/Power Entry Module

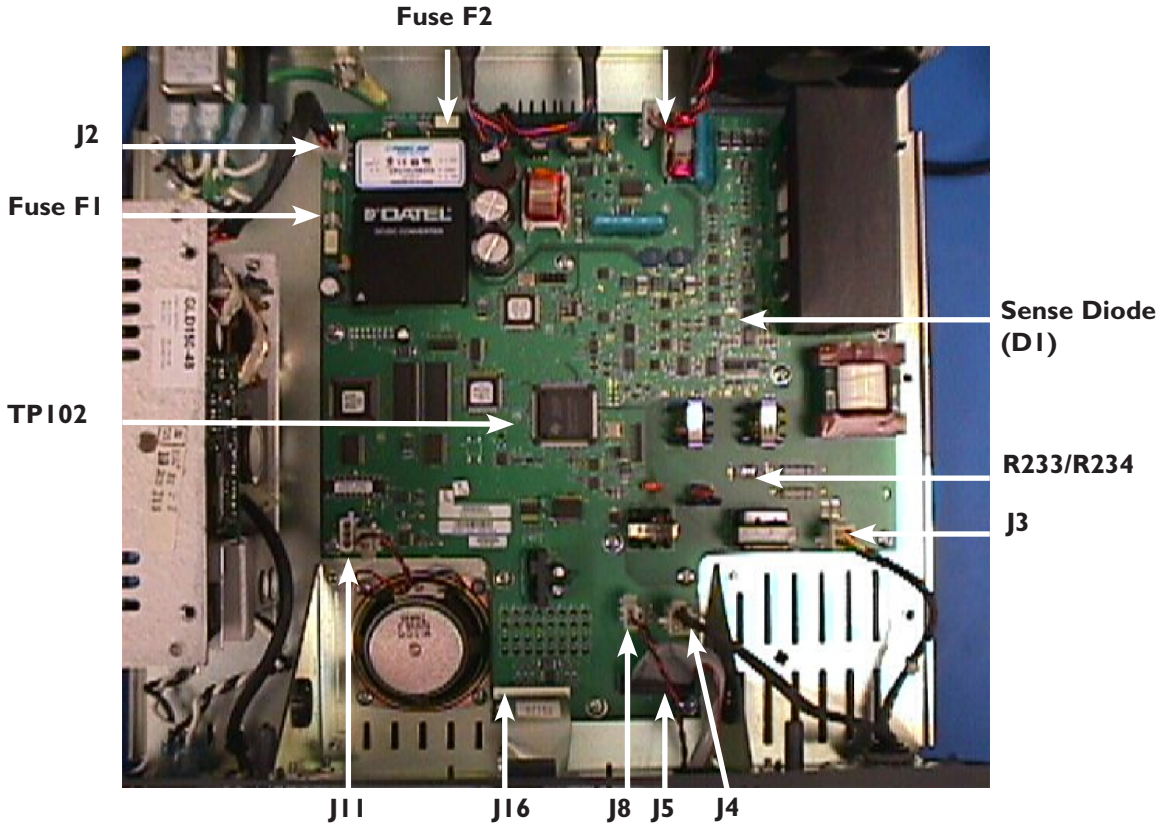


Fig. 12-3 Generator Board Component Locations

Generator Components

The following illustrations identify the components examined during troubleshooting.

Common Failures

The following sections describe some of the most common failures associated with the high-level parts of the HARMONIC Generator. There is no guarantee that this document will be able to address every possible failure; for issues other than those described below, please call 1-800-USE-ENDO for further assistance.

12-1 • Generator Failure

If the unit displays the **Error Code 1: Generator** error each time it is powered up, examine the error log to determine the cause of the error. To view the error log, enter the Developer/BME mode by simultaneously holding the STANDBY button and DOWN arrow button while powering up the unit. Using the UP and DOWN arrow buttons, scroll to page 1 to view the last 10 generator faults. If an error is listed consecutively, refer to the following table to determine the next action:

Code	Error	Action
16	FET_SOA_FAULT	Replace Generator Board or Send Unit to EES Service
20	MULTI_LEVEL_FAULT_281	Replace Generator Board or Send Unit to EES Service
22	GENERIC_PRERUN_FAULT	Replace Generator Board or Send Unit to EES Service
70	PCB_OVERTEMP_FAULT	Check to see if fan is working. If it is not, Replace Generator Board or Send Unit to EES Service
97	ADC_FAILURE	Replace Generator Board or Send Unit to EES Service
98	FET_BIAS_FAILURE	Replace Generator Board or Send Unit to EES Service
9A	SCI_FAILURE	Replace Generator Board or Send Unit to EES Service
9B	BEZEL_SWITCH_STUCK_FAILURE	Refer to Section 12-7 to troubleshoot the Front Bezel.
9C	EE_FAILURE	Replace Generator Board or Send Unit to EES Service
9D	EE_TIMEOUT_FAILURE	Replace Generator Board or Send Unit to EES Service
9E	AUD_TIMEOUT_FAILURE	Replace Generator Board or Send Unit to EES Service
9F	WATCHDOG_FAILURE	Replace Generator Board or Send Unit to EES Service
A0	NMI_ISR_FAILURE	Replace Generator Board or Send Unit to EES Service
A1	PHANTOM_ISR_FAILURE	Replace Generator Board or Send Unit to EES Service
A2	ROM_CRC_FAILURE	Replace Generator Board or Send Unit to EES Service
A3	DATA_MEM_FAILURE	Replace Generator Board or Send Unit to EES Service
A4	DSP_CORE_FAILURE	Replace Generator Board or Send Unit to EES Service
A5	DISPLAY_FAILURE	Replace Generator Board or Send Unit to EES Service
A6	POWER_SUPPLY_FAILURE	Refer to Section 12-4 to trouble shoot the power supply.
A7	SOFTWARE_INT_FAILURE	Replace Generator Board or Send Unit to EES Service
A8	MITIGATION_FAILURE	Replace the LCD Display
A9	STR_VAL_OUT_OF_BOUNDS_FAILURE	Replace Generator Board or Send Unit to EES Service
AA	UNKNOWN_FAILURE	Replace Generator Board or Send Unit to EES Service
AB	OVERCURRENT_FAILURE	Replace Generator Board or Send Unit to EES Service
AC	ILLEGAL_ADDR_FAILURE	Replace Generator Board or Send Unit to EES Service
AD	SPI_FAILURE	Replace Generator Board or Send Unit to EES Service
AE	AUDIO_FAILURE	Replace Generator Board or Send Unit to EES Service
AF	STACK_FAILURE	Replace Generator Board or Send Unit to EES Service
B0	VLVL_MITIGATION_FAILURE	Replace Generator Board or Send Unit to EES Service

12-2 • Hand Piece Failure

If the unit consistently displays the Error Code 5: Instrument error or Error Code 3: Hand Piece error upon being powered up, refer to Chapter 9 – High-Level System Troubleshooting to troubleshoot the Hand Piece Receptacle Assembly to determine if the problem is due to the Hand Piece or the Hand Piece Receptacle Assembly. If the Hand Piece Receptacle Assembly passes the continuity test and the Error Code remains, the problem is due to a faulty hand piece or instrument. Refer to Chapter 10 – Hand Piece Checkout to troubleshoot the problem.

12-3 • Unit shuts down immediately after turning on power switch.

This is an indication of an internal short that is causing the 48 VDC Power Supply to enter overload protection. Refer to Chapter 12 – Hardware Troubleshooting (Figure 12-8, page 51) to determine if there is a short and where the short is located.

12-4 • Unit will not power up.

If the unit is not powering up at all, meaning that the Cooling Fan, LCD, Front Bezel, and audible indicators are not functioning, it is an indication that Power supply is not supplying the Generator PCB with power or there is a problem with the Generator PCB itself. Refer to Chapter 12 – Hardware Troubleshooting (Figure 12-5, page 48) to troubleshoot the power supply section of the unit.

12-5 • Display does not light up.

If the LCD backlight is not functioning, yet the LCD is displaying the proper characters, refer to Chapter 12 – Hardware Troubleshooting (Figure 12-6, page 49) to help determine if the display is functioning incorrectly.

12-6 • Display is not working.

There are several indicators that could suggest that the Liquid Crystal Display (LCD) is not functioning properly. These indicators can include distorted graphics, no display, unreadable characters, or random characters. If random characters are displayed immediately upon the unit being powered up yet the display clears and the unit functions properly, replace the Generator Board. For all other issues, see Chapter 12 – Hardware Troubleshooting (Figure 12-6, page 49).

12-7 • Buttons on the Front Bezel are not responding.

If the unit does not respond to button depressions on the front bezel, refer to Chapter 12 – Hardware Troubleshooting (Figure 12-7, page 50) to help troubleshoot this issue.

12-8 • Front Bezel buttons or indicators are not illuminated.

If any of the buttons or indicators on the Front Bezel is not illuminated as they should be (for instance during the initial power up), refer to Chapter 12 – Hardware Troubleshooting (Figure 12-7, page 50).

12-9 • Cooling Fan is not working.

If the Cooling Fan is not operating and the unit is functioning properly, the generator will eventually overheat and will alert the user of an over-temperature fault. See Chapter 12 – Hardware Troubleshooting (Figure 12-10, page 53) to troubleshoot this issue.

12-10 • Buttons are illuminated simultaneously.

This issue pertains to two buttons that are normally not illuminated at the same time. For instance, if the **Standby** and **Ready** buttons are illuminated at the same time, or if the "ATTENTION: CONSULT ACCOMPANYING DOCUMENTATION" indicator is illuminated during normal use without an error displayed on the LCD. Should this problem occur, replace the Front Bezel.

Procedures

The following sections contain flowcharts that outline procedures to help determine whether the problem that is occurring is due to a high-level component failure or a failure associated with the Generator Board. Before executing any of these procedures, remove the Generator's cover, attach a known good instrument or test tip and power the unit up. Note: All specifications are +/-10% unless otherwise specified.

Hand Piece Assembly Receptacle Continuity Test

1. Power down the unit and remove the power cord.
2. Disconnect the wire harnesses from connectors J3 and J4.
3. Measuring between the Hand Piece Receptacle on the front panel and the Generator Board wire harness connectors, test the continuity of each of the wires according to the pinout table below (use Figure 12-4 as a reference):

PCB Connector	Connector Wire	Receptacle Pin
J3	Red	1
	Yellow	2
	Orange	3
	Green	4
J4	Brown	5
	Black	6
	Blue	7

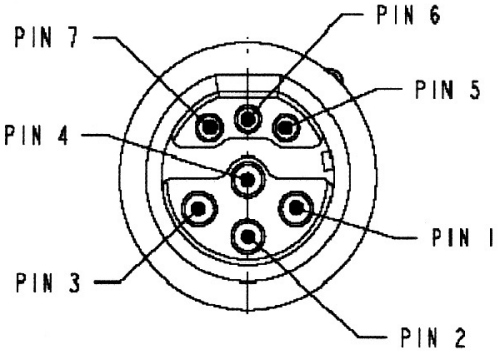
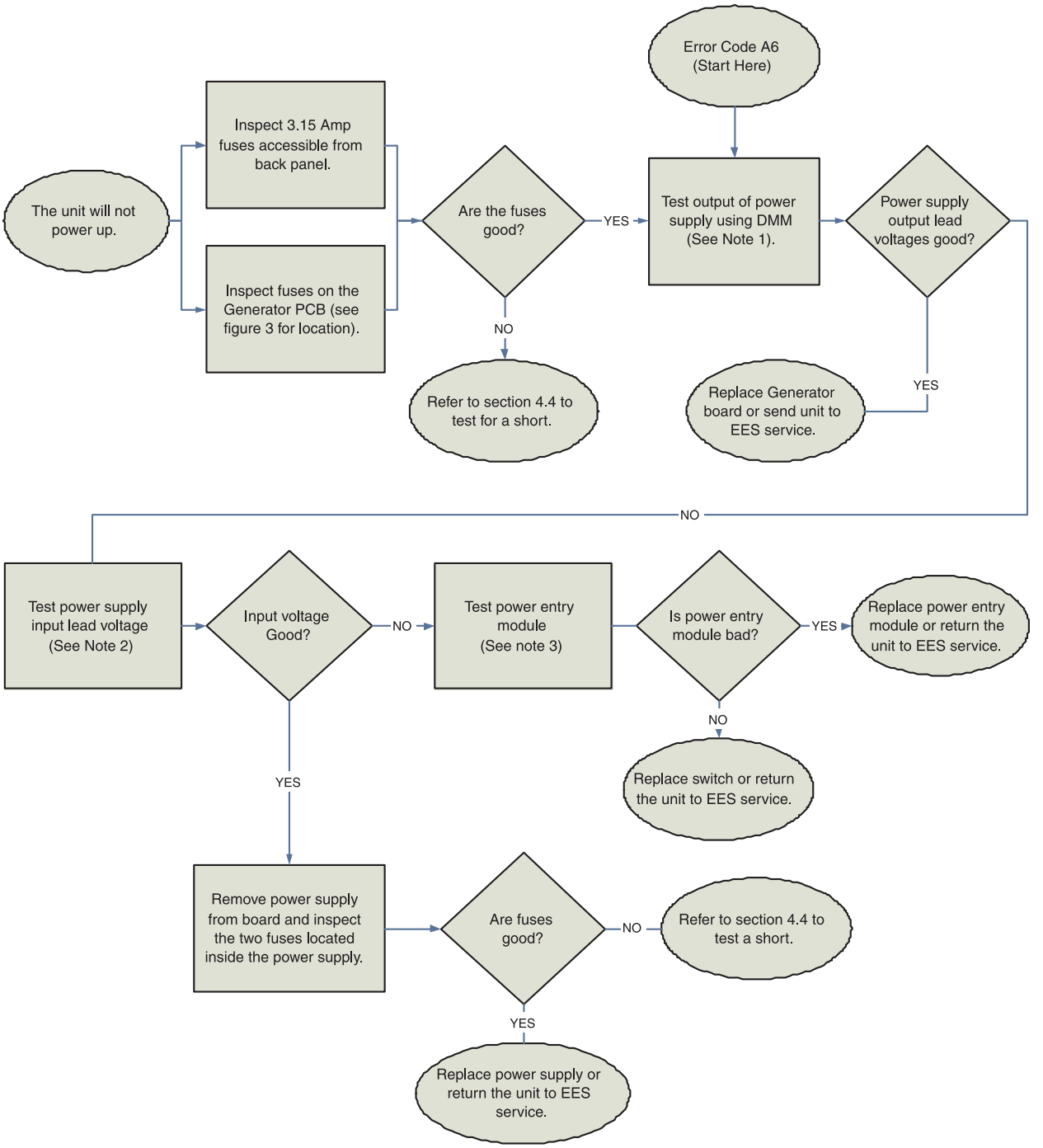


Fig. 12-4 Pinout Table

4. If any of the wires measure as "open", replace the Hand Piece Receptacle Assembly.
5. Upon visual inspection, if any receptacle pins appear worn, corroded, or loose, replace the Hand Piece Receptacle Assembly.

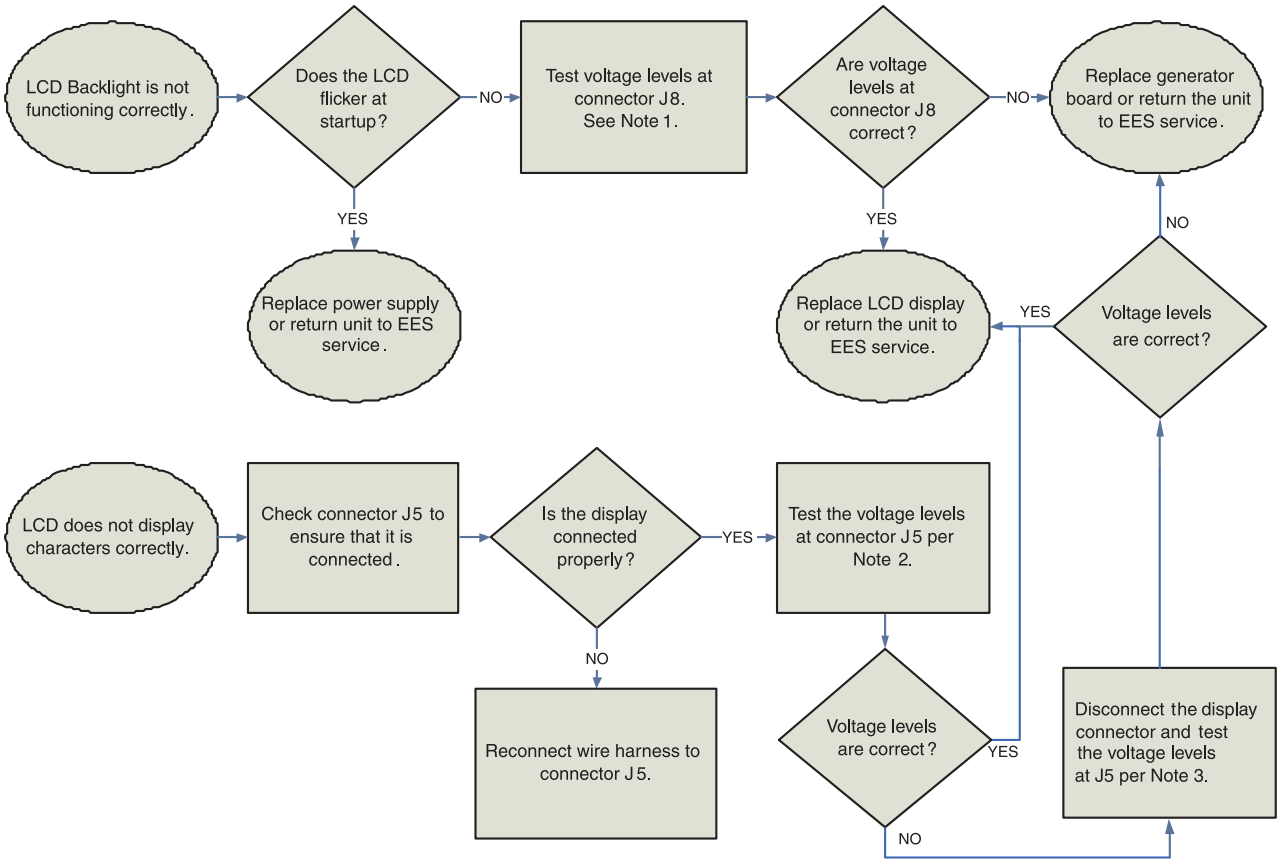

Error Code A6
(Start Here)
Inspect 3.15 Amp fuses accessible from back panel.
The unit will not power up.
Inspect fuses on the Generator PCB (see figure 3 for location).
Are the fuses good?
YES
Test output of power supply using DMM (See Note 1).
Power supply output lead voltages good?
NO
Refer to section 4.4 to test for a short.
Replace Generator board or send unit to EES service.
YES
NO
Test power supply input lead voltage (See Note 2)
Input voltage Good?
NO
Test power entry module (See note 3)
Is power entry module bad?
YES
Replace power entry module or return the unit to EES service.
NO
Replace switch or return the unit to EES service.
YES
Remove power supply from board and inspect the two fuses located inside the power supply.
Are fuses good?
NO
Refer to section 4.4 to test a short.
YES
Replace power supply or return the unit to EES service.

Note 1: Connector J2 output voltages should be as follows:
PIN 1: Return – Not Used
PIN 2: Return
PIN 3: +48VDC
PIN 4: +48VDC – Not Used

Note 2: Power down the unit and disconnect the power cord. Next, unplug the two power leads from the power switch that connects to connector J1 on the power supply. Replace the power cord and power the unit up, then verify with a DMM that the potential across these two leads is approximately 90-264VAC.
Note 3: Power down the unit and disconnect the power cord. Next, unplug the three leads from the power entry module. Replace the power cord and power the unit up, then verify with a DMM that the potential across the top two leads is approximately 90-264VAC.

Fig. 12-5 Power Supply Troubleshooting Flowchart

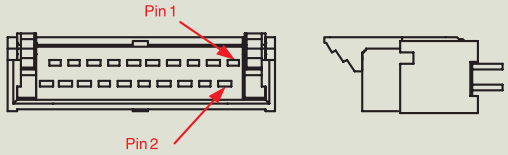
LCD Display


LCD Backlight is not functioning correctly.
Does the LCD flicker at startup?
NO
Test voltage levels at connector J8. See Note 1.
Are voltage levels at connector J8 correct?
NO
Replace generator board or return the unit to EES service.
YES
YES
NO
Replace power supply or return unit to EES service.
Replace LCD display or return the unit to EES service.
YES
Voltage levels are correct?
LCD does not display characters correctly.
Check connector J5 to ensure that it is connected.
Is the display connected properly?
YES
Test the voltage levels at connector J5 per Note 2.
NO
Reconnect wire harness to connector J5.
Voltage levels are correct?
YES
Disconnect the display connector and test the voltage levels at J5 per Note 3.
NO

Note 1: voltage Levels of J8 Connector.
PIN 1: +4VDC
PIN 2: GND

Note 2: Without unplugging the wire harness, carefully test the following pins on connector J5 with a DMM to ensure the power voltage levels and signal states exist (TP102 may be used as ground reference).

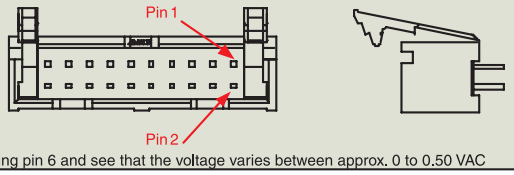
PIN 1: LCD_FRAME_GND: GND
PIN 2: LCD_VSS: GND
PIN 3: LCD_VDD: +5VDC
PIN 4: LCD_V0: -4VDC
PIN 7: LCD_Cen: +5VDC
PIN 8: LCD_C_Dn: +5VDC
PIN 10: LCD_RESET: +5VDC
PIN 20: LCD_VEE: -9VDC



Finally, verify that the generator board is sending data to the LCD by probing pin 11 and pressing the standby, test, up arrow, or down arrow. Observe the DMM when pressing any of these buttons and verify that the voltage changes.

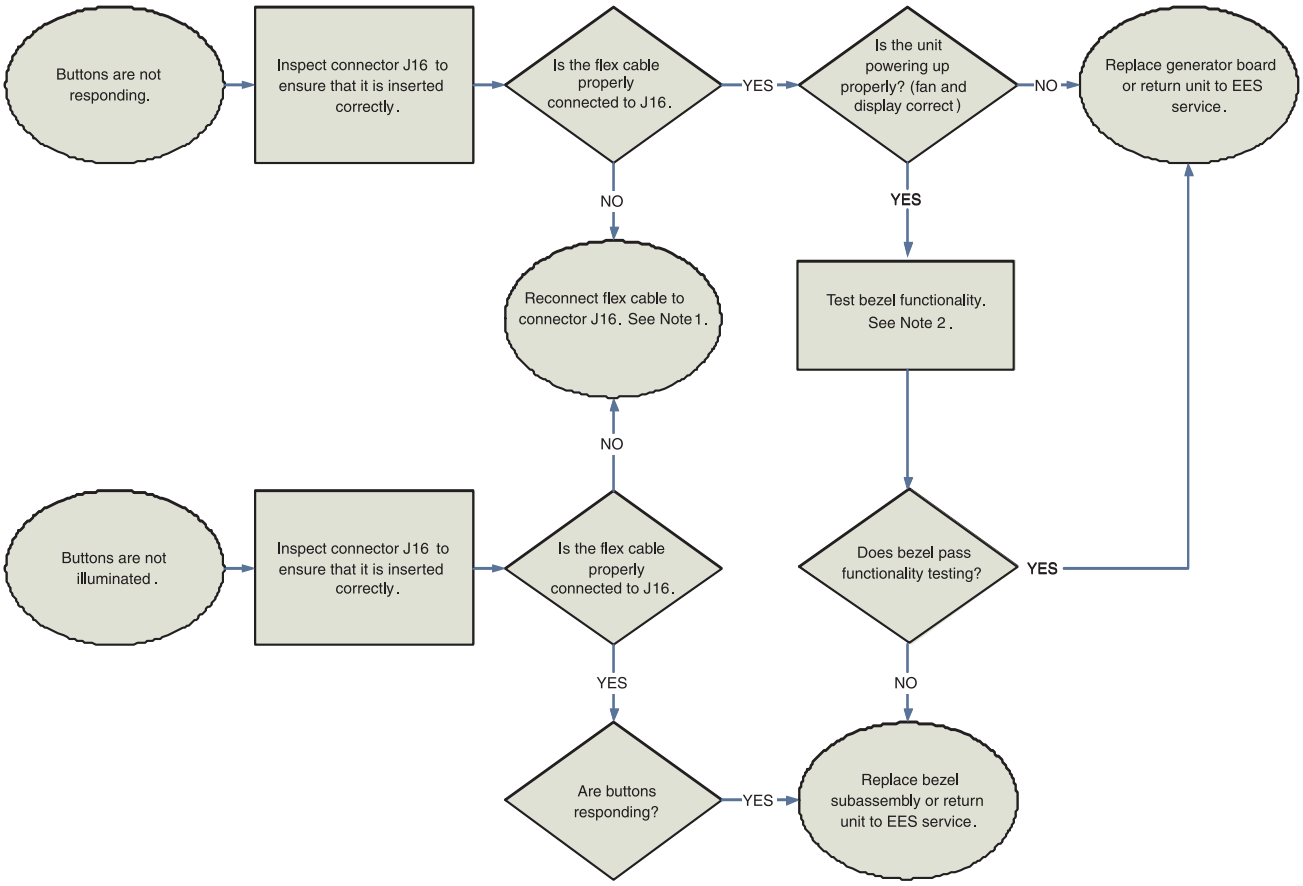
Note 3: After unplugging the wire harness, carefully test the following pins on connector J5 with a DMM to ensure the power voltage levels and signal states exist (TP102 may be used as ground reference).

PIN 3: LCD_VDD: +5VDC
PIN 4: LCD_V0: +5VDC
PIN 10: LCD_RESET: +5VDC
PIN 20: LCD_VEE: +5VDC



Finally, verify that the generator is attempting to communicate with the LCD by probing pin 6 and see that the voltage varies between approx. 0 to 0.50 VAC

Fig. 12-6 LCD Display Troubleshooting Flowchart


Buttons are not responding.
Inspect connector J16 to ensure that it is inserted correctly.
Is the flex cable properly connected to J16.
YES
Is the unit powering up properly? (fan and display correct)
NO
Replace generator board or return unit to EES service.
NO
YES
Reconnect flex cable to connector J16. See Note 1.
Test bezel functionality. See Note 2.
NO
Buttons are not illuminated.
Inspect connector J16 to ensure that it is inserted correctly.
Is the flex cable properly connected to J16.
Does bezel pass functionality testing?
YES
YES
NO
Are buttons responding?
YES
Replace bezel subassembly or return unit to EES service.

Note 1: Power the unit down and disconnect the power cord before connecting or disconnecting the flex cable. To release the flex cable from the connector, grasp both ends of the connector and lift up. To connect the flex cable, make sure that the release clip is pulled up, then fully insert the cable. Finally, push down on the release clip to lock the cable into place.

Note 2: Using TP102 (located on the generator board as shown in Figure 12-3) as a ground reference, measure the voltages at the following points on the board to ensure that the buttons are functioning properly. (Measurements should be taken on the side of the resistor that connects to connector J16).

R15 – STANDBY
R16 – DOWN ARROW
R17 – UP ARROW
R18 – TEST
R19 – HAND

There should be +5VDC present at these resistors. If +5VDC is not present, unplug the flex cable from connector J16. If +5VDC is still not present at these points, then the generator board is not functioning correctly. If +5VDC is present after disconnecting the flex cable, then the front bezel is not functioning properly. Otherwise, observe the voltage measured while pressing the corresponding button; this should cause the button to pull low to <1V. If the voltage does not pull low, then the bezel is not functioning properly.

Fig. 12-7 Front Bezel Troubleshooting Flowchart

Unit Short Test

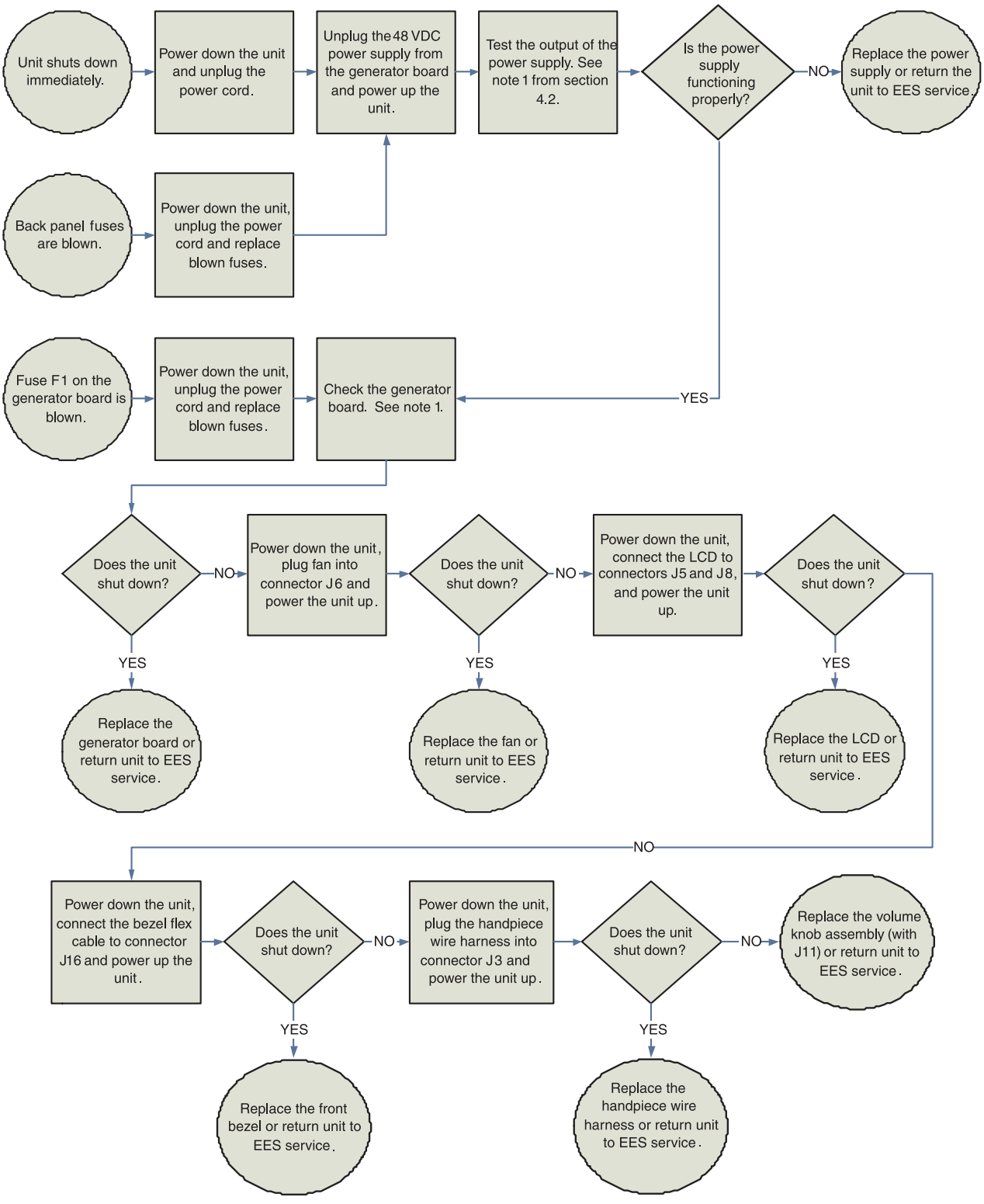

Unit shuts down immediately.
Power down the unit and unplug the power cord.
Unplug the 48 VDC power supply from the generator board and power up the unit.
Test the output of the power supply. See note 1 from section 4.2.
Is the power supply functioning properly?
NO
Replace the power supply or return the unit to EES service.
Back panel fuses are blown.
Power down the unit, unplug the power cord and replace blown fuses.
Fuse F1 on the generator board is blown.
Power down the unit, unplug the power cord and replace blown fuses.
Check the generator board. See note 1.
YES
Does the unit shut down?
NO
Power down the unit, plug fan into connector J6 and power the unit up.
Does the unit shut down?
NO
Power down the unit, connect the LCD to connectors J5 and J8, and power the unit up.
Does the unit shut down?
YES
Replace the generator board or return unit to EES service.
YES
Replace the fan or return unit to EES service.
YES
Replace the LCD or return unit to EES service.
NO
Power down the unit, connect the bezel flex cable to connector J16 and power up the unit.
Does the unit shut down?
NO
Power down the unit, plug the handpiece wire harness into connector J3 and power the unit up.
Does the unit shut down?
NO
Replace the volume knob assembly (with J11) or return unit to EES service.
YES
Replace the front bezel or return unit to EES service.
YES
Replace the handpiece wire harness or return unit to EES service.

Fig. 12-8 Unit Short Test Troubleshooting Flowchart

Unit Short Test

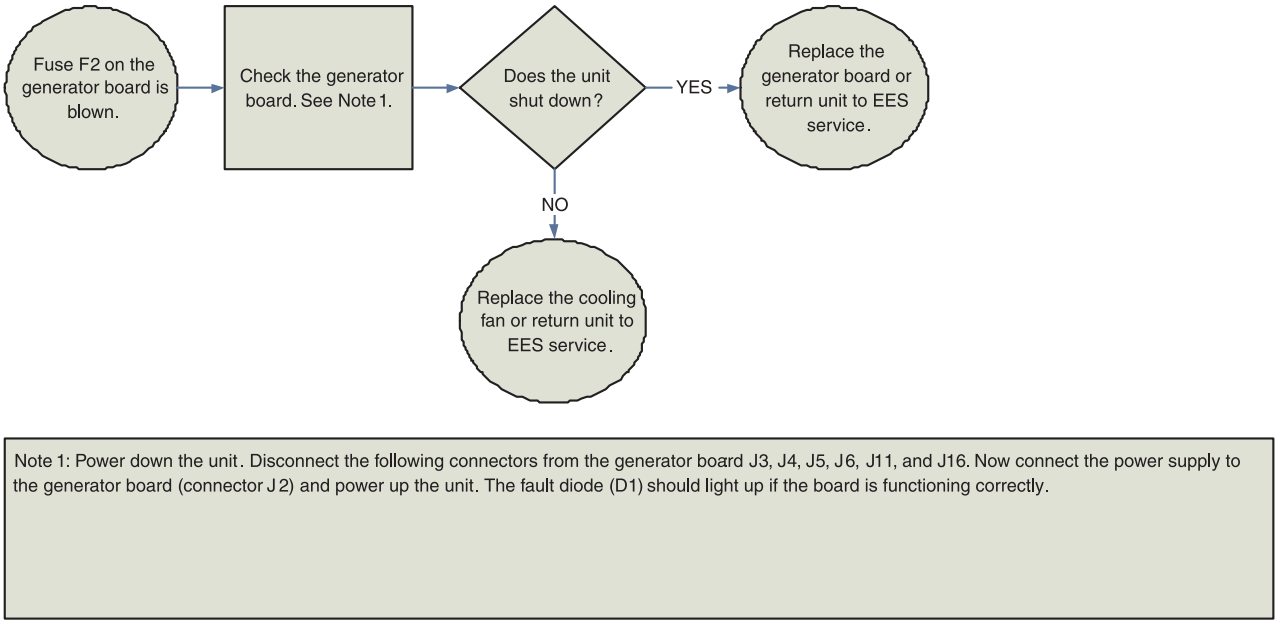
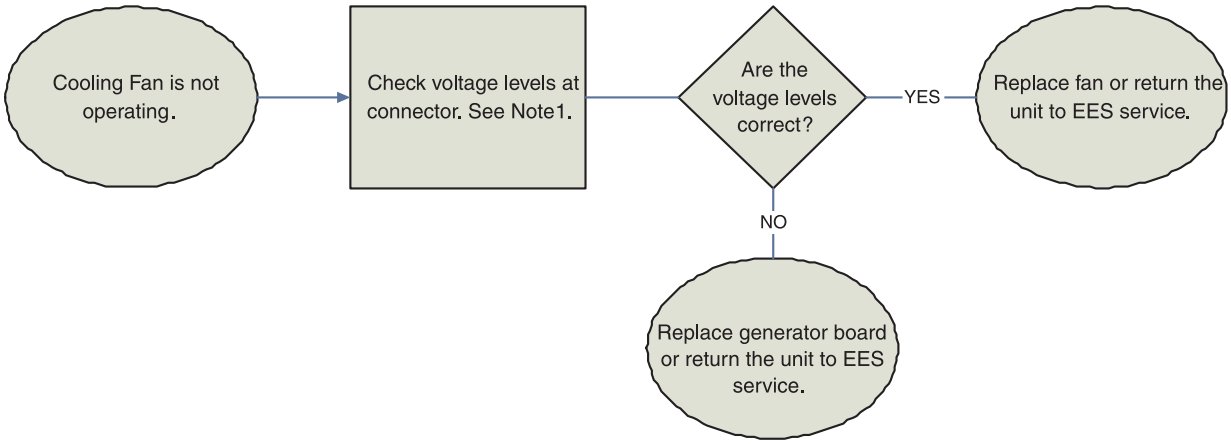

Fuse F2 on the generator board is blown.
Check the generator board. See Note 1.
Does the unit shut down?
YES
Replace the generator board or return unit to EES service.
NO
Replace the cooling fan or return unit to EES service.
Note 1: Power down the unit. Disconnect the following connectors from the generator board J3, J4, J5, J6, J11, and J16. Now connect the power supply to the generator board (connector J2) and power up the unit. The fault diode (D1) should light up if the board is functioning correctly.

Fig. 12-9 Unit Short Test Troubleshooting Flowchart (Cont.)

Cooling Fan


Cooling Fan is not operating.
Check voltage levels at connector. See Note1.
Are the voltage levels correct?
YES
Replace fan or return the unit to EES service.
NO
Replace generator board or return the unit to EES service.

Note 1: Remove wire harness from connector J6 on the generator PCB. Measure the voltage levels at connector J6 to ensure they are at the proper levels.

Pin 1: +48V
Pin 2: GND

Fig. 12-10 Cooling Fan Troubleshooting Flowchart

Footswitch Activation

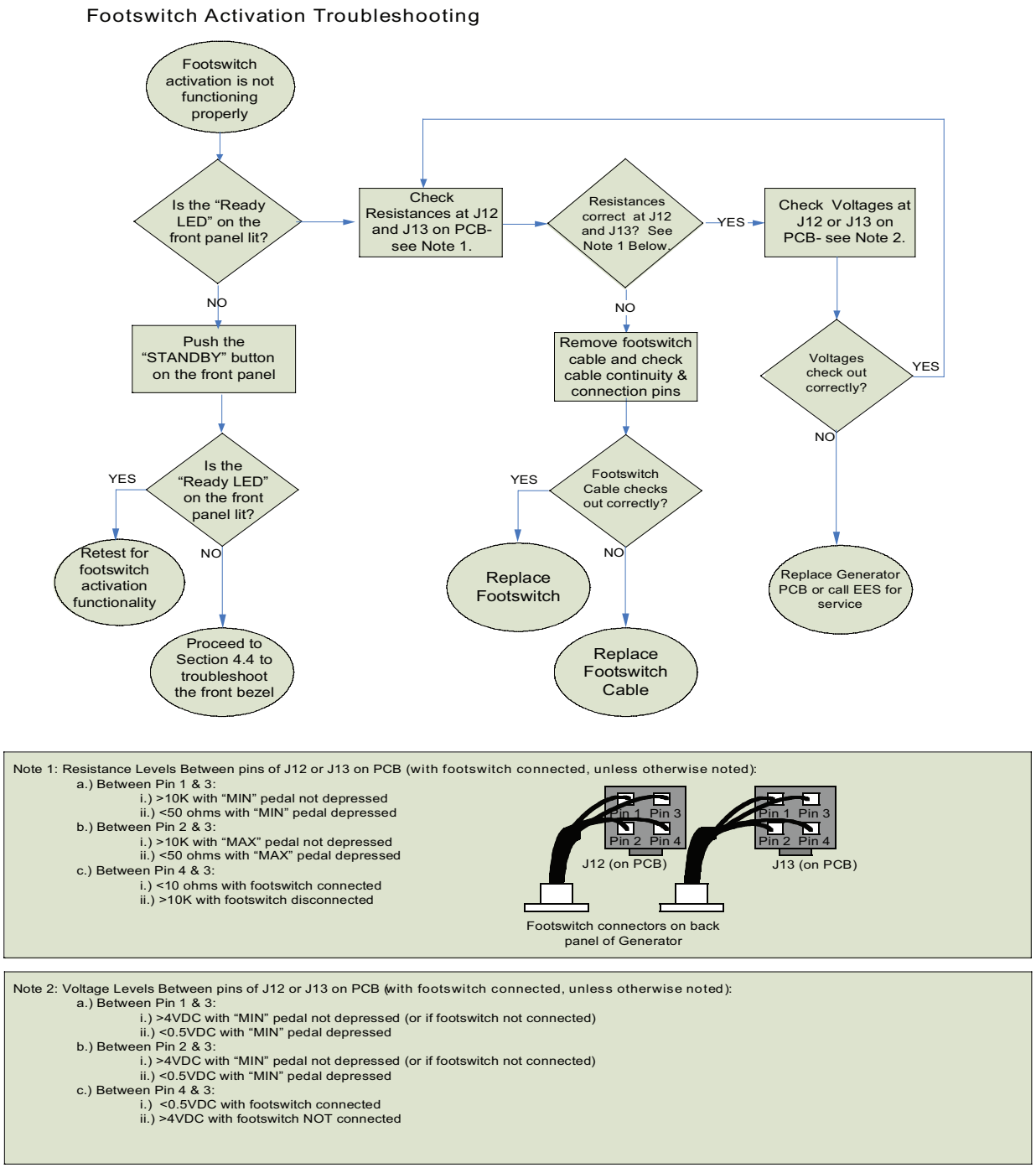


Fig. 12-11 Footswitch Activation Troubleshooting Flowchart

Handswitch Activation

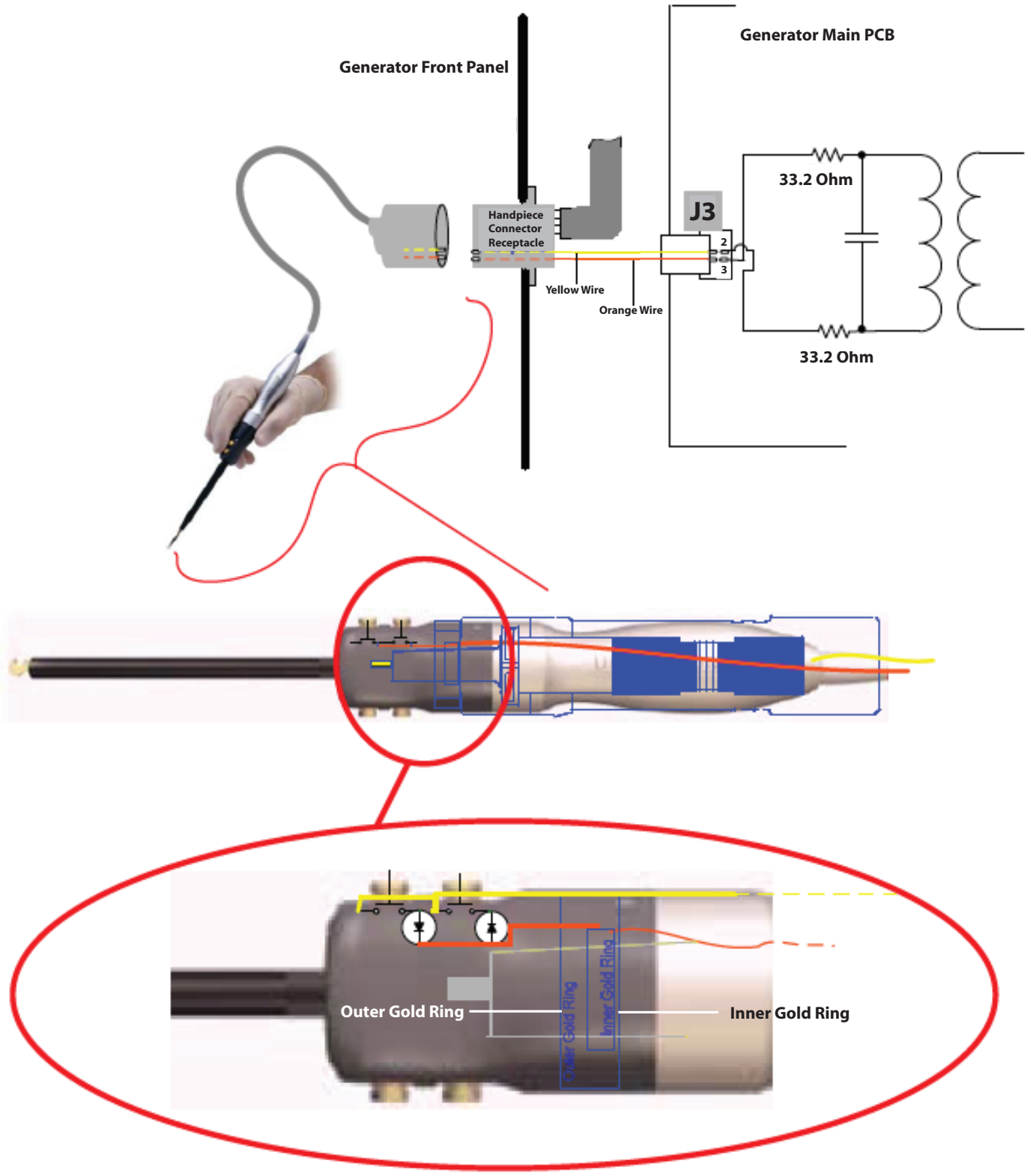


Fig. 12-12 Handswitch Activation Troubleshooting Flowchart

Required Schedule

Calibration is **recommended** on the HARMONIC Generator 300 every **5 years.**

Proof of calibration should be documented according to hospital procedures.

Generators can be returned to Ethicon Endo-Surgery for calibration, but this is not covered in the warranty. A minimal charge will be assessed. This can be done by calling 1-800-USE-ENDO (U.S. Customers). International Customers should contact their Ethicon Endo-Surgery representative for assistance.

Calibration Procedures

Complete the following Calibration procedures every 5 years according to hospital procedures.

Caution: Use proper hospital safety procedures when performing a calibration.

For best accuracy, take the measurements required in step 16 and step 27 of the procedure ONLY as follows:
One test lead of the DMM touching R234 on the side that doesn't connect to R233. This lead will need to be held in place manually as there is nothing to connect an alligator clip to. (For best accuracy, do not clip to C177 or any other node connection point on the circuit board.) The second test lead can be clipped to R229 on the lead that is connected directly to R233.

There are two calibration sub-processes that must be executed in the following order:
- Calibration One
- Calibration Two

Calibration One (Write Current Calibration)

This section describes the requirements for calibrating the output current level of the generator.

Minimum Accuracy Requirements:
- True RMS AC Voltage (Voltage Range 100mV to 1000mV, 23°C +/- 5°C):
- 3hz - 5hz: 1.00% of reading + 0.04% of range
- 5hz - 10hz: 0.35% of reading + 0.04% of range
- 10hz - 20Khz: 0.06% of reading + 0.04% of range
- 20Khz - 50Khz: 0.12% of reading + 0.04% of range
- 50Khz - 100Khz: 0.60% of reading + 0.08% of range
- 100Khz - 300Khz: 4.00% of reading + 0.50% of range

Note: For best accuracy, take the measurements required in step 16 and step 27 of the procedure ONLY as follows: One test lead of the DMM touching R234 on the side that doesn't connect to R233. This lead will need to be held in place manually as there is nothing to connect an alligator clip to. (For best accuracy, do not clip to C177 or any other node connection point on the circuit board.)

The second test lead can be clipped to R229 on the lead that is connected directly to R233.

Note: "Power up into BME Mode" includes taking the following steps:
- Power down unit
- Wait 5 seconds
- Power up Unit while simultaneously holding the "STANDBY" and "DOWN ARROW" keys

Procedure:
1. Remove the generator cover.
2. Connect the foot switch assembly to the generator or mount the hand switching adapter onto the hand piece.
3. Connect the hand piece to the generator.
4. Attach a test tip to the hand piece, and torque on using a torque blade wrench.
5. Power up the generator into BME Mode.

6 Scroll to page 2.

7 Record the 'Current Setpoint' value: _____mA

8 By specification, 75% of the value recorded in step 7 is the Anticipated Level 3 current. Calculate and record this value by **multiplying** the step 7 value above, by **0.75**. _____mA

9 Scroll to page 17.
10 Turn the volume knob fully to the left (counter-clockwise).
11 Press the "TEST" key repeatedly until "Value Not Accepted" is flashed on the display. Fail_____ Pass_____
The unit is now intentionally uncalibrated. This can be verified by scrolling to page 21 and inspecting the "Current Write Cal:" The value should be 5060. Fail_____ Pass_____

12 Put the generator into BME Ready state by pressing the 'STANDBY' Key.
13 Ensure the test tip is prepared to activate in air and is not in contact with anything during activation.
14 Activate at level 3 by pressing the MIN footswitch or hand switching adapter buttons.
15 After the pre-run test is complete, continue activating at level 3, and measure the VAC RMS across the series combination of R233 and R234, using the Digital Multimeter (DMM). Record the value to four digits of precision. _____mA
16 Deactivate the hand piece by releasing the foot switch or hand switch button.
17 Put the generator into BME Standby State by pressing the 'STANDBY' Key.
18 Scroll to page 17.
19 By turning the volume knob, dial in the value read on the DMM in step 16. (A number is displayed on the LCD, which changes as the knob is turned).
20 Press the "TEST" key one time (only one time).
"Value Accepted" should flash. Fail_____ Pass_____
21 Power off the unit for at least 5 seconds.
22 Power up the generator into BME Mode.
23 Put the generator into BME Ready State by pressing the 'STANDBY' Key.
24 Ensure the test tip is prepared to activate in air and is not in contact with anything during activation.
25 Activate at level 3 by pressing the MIN footswitch or hand switching adapter buttons.
26 After the pre-run test is complete, continue activating at level 3, and measure the VAC RMS across the series combination of R233 and R234, using the DMM as in step 15 above. Record the value to four digits of precision: _____mA
27 Verify the current in step 26 is within 1% of the value calculated in step 8. If not, carefully re-execute this test procedure again (up to three times). Fail_____ Pass_____
28 Power OFF the generator for at least 5 seconds and continue to the CALIBRATION TWO procedure.

GEN04 Serial Number:_____

Technician Signature:_____**Date:**_____

Calibration Two (Read Current Calibration)
This section describes the requirements for calibrating the monitored (read) current level of the GEN04 Generator.

Note: "Power up into BME Mode" includes taking the following steps – which are also contained in the service manual (included here for reference):

- Power down unit
- Wait 5 seconds
- Power up unit while simultaneously holding the "STANDBY" and "DOWN ARROW" keys

Procedure:

1 Power up the generator into BME Mode.
2 Scroll to page 2.
3 Record the 'Current Setpoint' value. _____mA
4 By specification, 75% of the value recorded in step 3 is the anticipated Level 3 current. Calculate and record this value by **multiplying** the step 3 value above, by **0.75**. _____mA
5 Put the generator into BME Ready State by pressing the 'STANDBY' Key.
6 Ensure the test tip is prepared to activate in air and is not in contact with anything during activation.
7 Activate at level 3 by pressing the "MIN" footswitch or "MIN" hand switching adapter buttons.
8 Continue activating the generator at level 3 for at least 1 second after the pre-run test is complete.
9 Deactivate the hand piece by releasing the footswitch or hand switching adapter buttons.
10 Put the generator into BME Standby State by pressing the 'STANDBY' Key.
11 Scroll to page 18.
12 Press the 'TEST' key one time (only one time) to accept the calibration current value.
13 The text "Value Accepted!" should flash if the calibration procedure was successful. Fail_____ Pass_____
14 Record the current displayed on the screen. _____mA
15 Power the unit off for at least 5 seconds.
16 Power the unit into BME Mode.
17 Enter BME Ready State by pressing the "STANDBY" Key.
18 Ensure the test tip is prepared to activate in air and is not in contact with anything during activation.
19 Activate at level 3 by pressing the "MIN" footswitch or "MIN" hand switching adapter buttons.
20 Continue activating the generator at level 3 for at least 1 second after the pre-run test is complete.
21 Deactivate the hand piece by releasing the footswitch or hand switching adapter buttons.
22 Go to BME Standby State by Pressing the "STANDBY" Key.
23 Scroll to page 18.
24 Record the 'I (LEVEL 3)' current displayed on page 18. _____mA
25 Verify that the reading is within 1% of the value calculated in step 4. If not, carefully re-execute both CALIBRATION ONE & CALIBRATION TWO procedures again (up to three times.) Fail_____ Pass_____
26 Power OFF the Generator.

GEN04 Serial Number:_____

Technician Signature:_____**Date:**_____

Product Codes	**Required Components for System Operation:** GEN04: Generator 300 Hand Piece: See package inserts for compatibility (including Test Tip and Blade Wrench). **Instruments and Adaptors:** Contact your Ethicon Endo-Surgery representative for information about instruments available for use with this system. Some instruments may require use of an adaptor. **Optional Components:** FSW01: Foot Switch[2] HSA07: Hand Switch[1,2] CRT01: Cart [1] Refer to separate product insert supplied with this component. [2] At a minimum, either the foot switch or the hand switching adaptor is required to operate the generator. When the hand switching adaptor is used, availability of the foot switch is recommended.
Degree of Protection Against Electric Shock	Type CF Applied Part
Class of Protection Against Electric Shock	Class I
Safety Standards	EN 60601
Degree of Protection Against Harmful Ingress of Water	Generator: Ordinary equipment Footswitch: IPX8
Safety Classification	UL 2601-1 CSA C22.2 601.1 EN 60601-1
Mains Input	Voltage: 100-240 VAC Frequency: 50/60 Hz Current Consumption: 3 amp
Ambient Operating Conditions	Temperature: 10˚C to 40˚C Humidity: 10-90% non-condensing Atmospheric Pressure Range: 700hPa-1060hPa
Transport and Storage Conditions	Temperature: -35˚C to +54˚C Humidity: 10-95% non-condensing Atmospheric Pressure Range: 700hPa-1060hPa

Date of Manufacture

The date of manufacture may be determined by viewing the serial number on the rear panel of the generator. The fourth and fifth characters indicate the year of manufacture as follows:
GN401 = year 2001
GN402 = year 2002
GN403 = year 2003
GN404 = year 2004
GN405 = year 2005
GN406 = year 2006
GN407 = year 2007

Power Cord

The GEN04 is supplied with a North American removable power cord set with the following characteristics:
Plug Style: NEMA 5-15 (clear) North American Hospital Grade
Receptacle: IEC 60320 C13 with straight non-angled cord entry
Cord Length: 4.6 meters nominal
Current Rating: 13A
Voltage Rating: 125 VAC minimum
Wiring Code: North American
Cordage Description: SJT (UL) or SJT (CSA)
Conductors: 16 AWG 3C
Agency Approvals Required: UL and CSA

If an International power cord is required, the user should select a removable power cord set with the following characteristics:
Plug Style: as needed by particular country requirements
Receptacle: IEC 60320 C13 with straight non-angled cord entry
Cord Length: 2.44 - 4.6 meters nominal
Current Rating: 10A
Minimum conductor size cross-sectional area: 1.0 mm^2 copper
Voltage Rating: 250 VAC minimum
Wiring: international
Cordage Type: HAR
Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV

Duty Cycle

Duty Cycle is determined by hand piece and instrument in use. For duty cycle information, refer to applicable instrument(s) and hand piece inserts and/or Chapter 7 – Warnings and Precautions of the HARMONIC Generator 300 System User Manual.

Weight (unpacked)

Generator: 7.48 kg nominal

Cart: 42.0 kg nominal

Overall Dimensions

Generator 300 (HxWxD): 5.3” (13 cm) x 14.5” (37 cm) x 15.2” (39 cm)

Cart (HxWxD): 37.3” (95 cm) x 17.7” (45 cm) x 27.6” (70 cm), including handle

Disposal

Some internal components of the generator, foot switch and foot switch cable contain lead. Disposal should be performed according to local requirements and regulations.

Torque Requirements

Item	Torque	Units	Thread Locker	QTY	Comments
Front Bezel, Volume Control	6	In-Lb	No	1	long socket required
Front Bezel, Hand Piece Receptacle	24	In-Lb	No	1	torqued with open-end torque wrench
Front Bezel, LCD	7	In-Oz	Yes	4	Phillips, Loctite 222
Front Bezel to Chassis	11	In-Lb	No	5	Phillips
Fan to Chassis	11	In-Lb	No	4	standard socket
Footjack Connectors to Chassis	11	In-Lb	No	2	long socket required
Speaker to Chassis	11	In-Lb	No	4	Phillips
Silver Ribbon Cable from Front Panel Switches	11	In-Lb	No	1	Phillips
Fuse Holders to Chassis	6	In-Lb	No	2	long socket required
Power Entry Module to Chassis	6	In-Lb	No	2	Phillips & hold the nut
Ground Pin-to-Chassis	6	In-Lb	No	1	Special tool used to engage nut
Ground Pin Nut	18	In-Lb	No	1	standard socket
Ground Wires to Chassis	18	In-Lb	No	2	Phillips
Power Supply to Chassis	7	In-Lb	Yes	2	Phillips, Loctite 222
Generator PC Board to Chassis	18	In-Lb	No	15	Phillips
Cover to Chassis	18	In-Lb	No	11	Phillips

Power Level Adjustment

Upon start-up, the generator defaults to power level 3 (MIN) and 5 (MAX). The minimum (MIN) power level is user-settable from power levels 1 to 5. To adjust the power level, depress the UP/DOWN arrow button to the left of the MIN power level display. Set the power level based on surgeon preference and/or recommendations provided in the instrument's package insert (for more information, see Power Levels section in Chapter 2 – General Description).

Audible Activation Tone Adjustment

The generator has three activation tone sets from which to choose (the mid-pitch tone is factory set). To choose another tone:

1. Switch power off.
2. Switch power on. Then immediately depress and hold both the STANDBY and HAND ACTIVATION buttons. When the graphic shown in Fig. 11-1 appears on the display, release the STANDBY and HAND ACTIVATION buttons.
3. While in the Tone Selection mode, the generator will automatically sequence through the available tone pitches. To select a tone, depress any button on the control panel. The generator will return to Standby mode. The tone chosen will be saved until it is changed again by accessing the Tone Selection mode.
4. Adjust tone volume by turning the knob on the lower left corner of the control panel. A tone will sound to indicate the volume level selected.

   Note: For safety reasons, the audible tone may not be disabled. The audible tone volume for alarms cannot be changed.

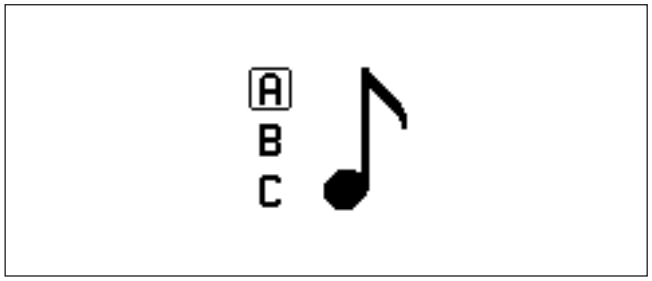


Fig. 15-1 Display: Tone Selection A

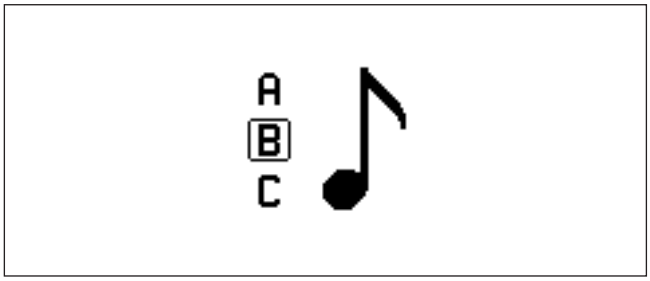


Fig. 15-2 Display: Tone Selection B

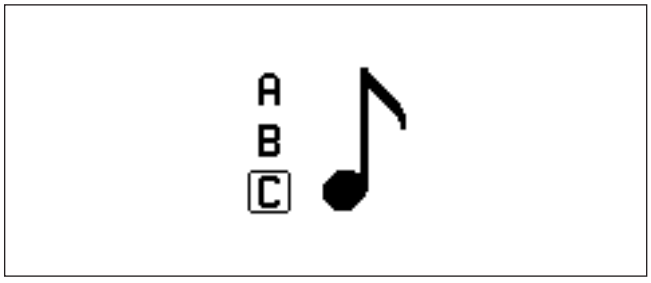


Fig. 15-3 Display: Tone Selection C

Repair Strategy

- Thorough knowledge of the HARMONIC Generator 300 System User Manual and this manual is mandatory prior to attempting any repair.
- Loaner units may be provided free of charge for units which are being repaired under warranty.
- Calibration is not covered by any warranty. There will be a nominal charge for the manufacturer to perform the Calibration Procedure.
- Only those replacement parts designated in the Parts List are available for sale.
- Use only Ethicon Endo-Surgery approved replacement parts. Your Ethicon Endo-Surgery representative will be happy to assist you in obtaining replacement parts.
- Replacement parts can be purchased from Ethicon Endo-Surgery by calling 1-800-USE-ENDO (U.S. Customers) or by contacting an Ethicon Endo-Surgery representative (outside the U.S.).

Available Resources

- An Ethicon Endo-Surgery Sales Representative is available for assistance.
- The Ethicon Endo-Surgery Customer Response Center is available for Biomedical engineering support by calling 1-800-USE-ENDO (U.S. Customers). Customers outside the U.S. should contact their Ethicon Endo-Surgery representative for assistance.

Service and Repair Returns

U.S. - All service inquiries in the US should be initiated by calling 1-800-USE-ENDO. A Customer Service representative will walk the customer through the equipment return process and identify the location where to ship the equipment.

Outside the U.S. – Customers should contact their Ethicon Endo-Surgery representative for instructions.

Prior to sending your generator in for service:

- Obtain a Return Goods Authorization Number by calling 1-800-USE-ENDO.
- Package the generator in the original packaging with the tag indicating the return address information, a description of the problem, and your Return Goods Authorization Number.

Note: Warranty may be voided if the unit is not returned to the service center in the original packaging or equivalent packaging which will protect the unit during shipment.

- Ship the generator prepaid to Ethicon Endo-Surgery Service Department.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Ohio, U.S.A.

Ethicon Endo-Surgery warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below.
Ethicon Endo-Surgery's obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to Ethicon Endo-Surgery or its Distributor within the applicable time period shown below and which examination disclosed, to Ethicon Endo-Surgery's satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by Ethicon Endo-Surgery, (2) repaired or altered outside Ethicon Endo-Surgery's factory in a way so as to, in Ethicon Endo-Surgery's judgement, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry.

Ethicon Endo-Surgery's products are warranted for the following periods after delivery to the original purchaser:

Hand Pieces	Nine (9) Months, Parts and Labor
Generators	One (1) Year, Parts and Labor (Extended warranties available. Call 1-800-USE-ENDO for more information.)
Carts	One (1) Year, Parts and Labor
Foot Switches and Cables	One (1) Year, Parts and Labor
Sterilization Tray	One (1) Year, Parts and Labor

UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW. Ethicon Endo-Surgery neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery's products. There are no warranties that extend beyond the terms hereof.

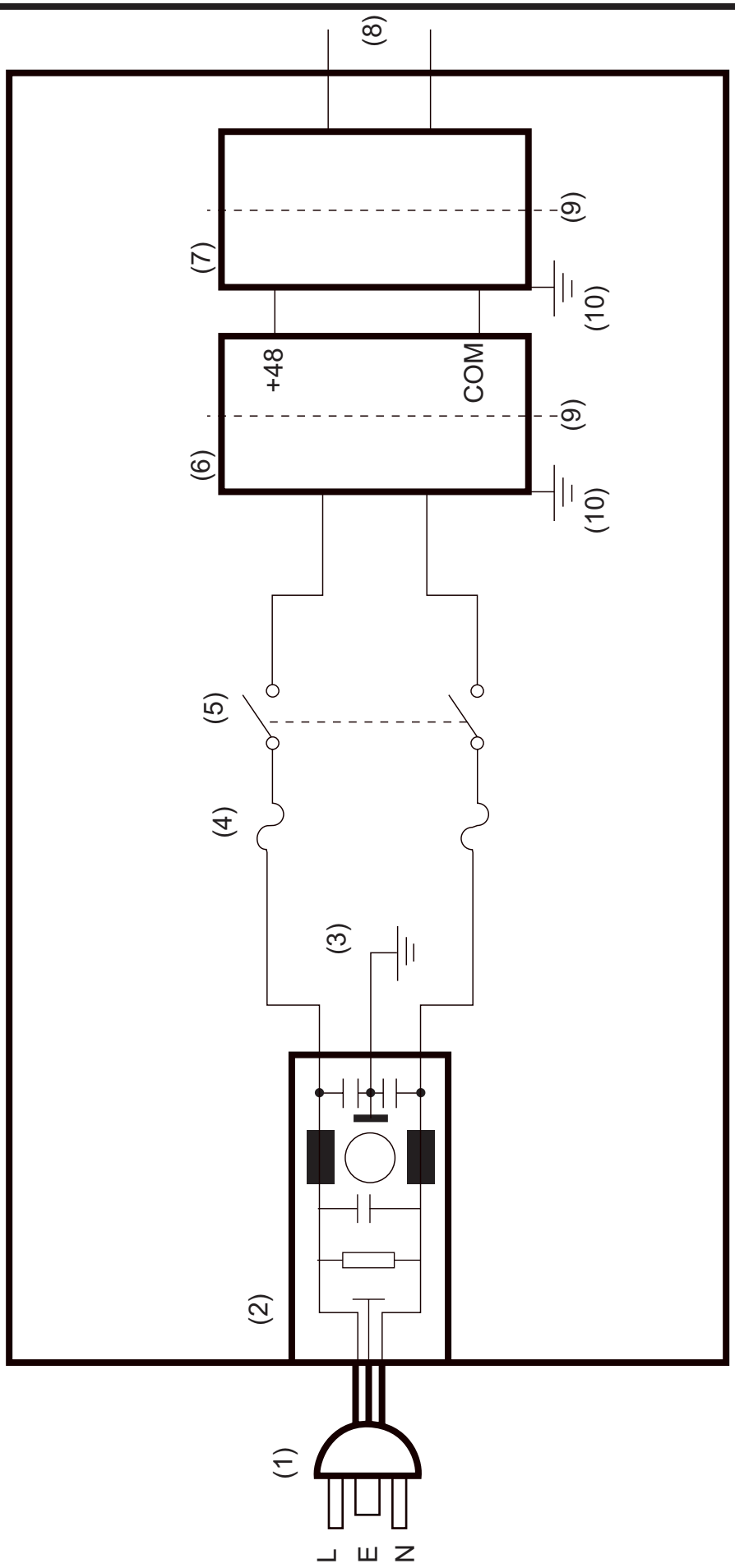
Ethicon Endo-Surgery reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

	On
	Off
	Type CF Applied Part
	Lot
	Temperature
	Relative Humidity
	Attention - Consult Accompanying Documents/See Instructions For Use
	Non-Sterile
	Date of Manufacture
	Fragile
	This end up
	Keep dry
	Increase/Decrease
	Serial Number
	Equipotential

	Fuse
	Safe working load
	Test
	Hand Activation
	Volume
	Minimum
	Maximum
	Ready
	Standby
	Reorder Number
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	ON/OFF Time for Intermittent Operation. Refer to the individual package insert and/ or Chapter 1 – Warnings and Precautions for additional specifications.
	Foot switch
	Manufacturer

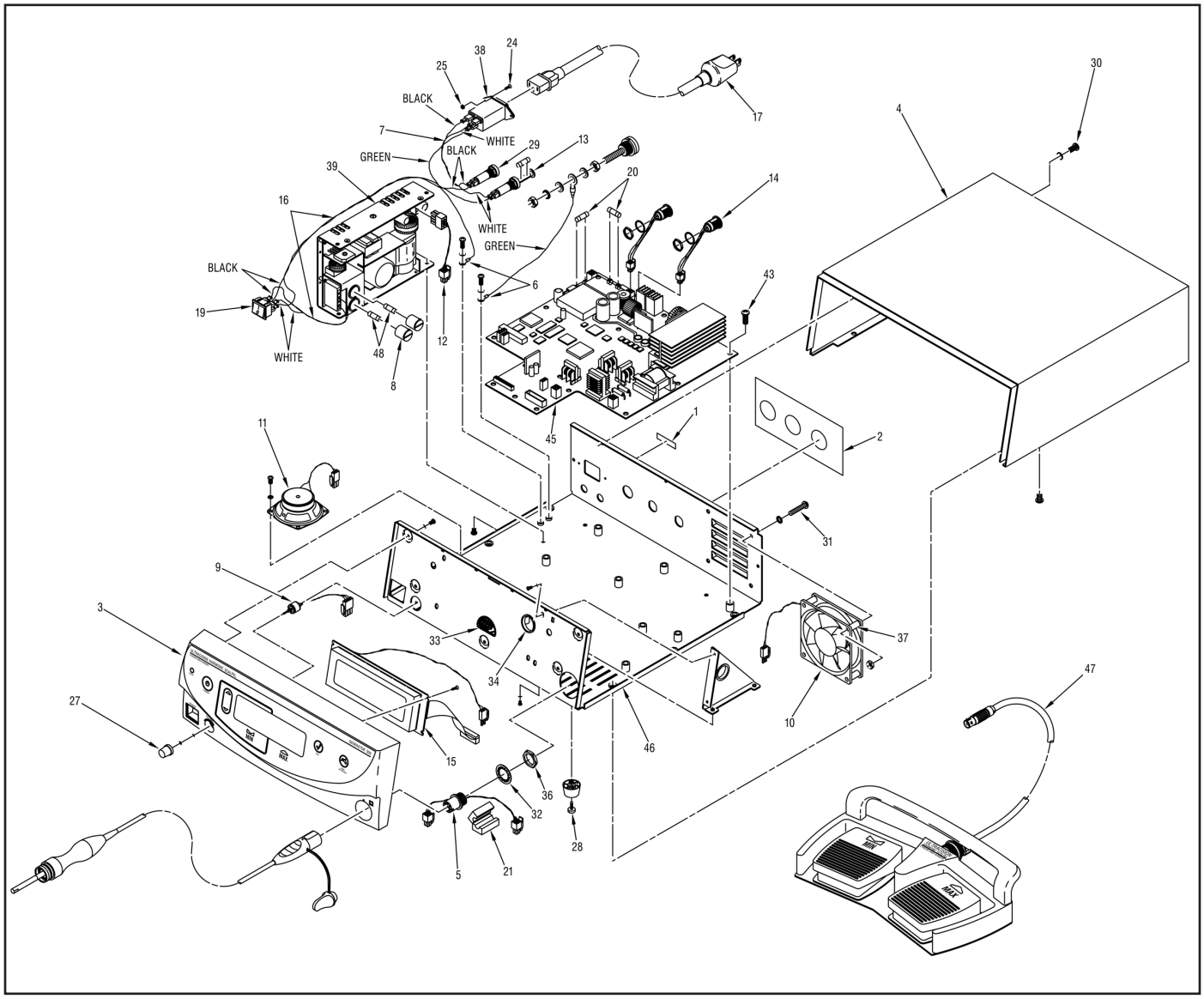
	Authorized Representative in the USA.
	Electrical and electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before returning waste.
	The electronic information product (EIP) has met the requirements set forth by the People's Republic of China for marking of EIPs, and can be used during its environmental protection use period of 50 years. After the environmental protection period has expired, the EIP should be recycled. Applicable in the People's Republic of China.

Mains Power Wiring Diagram for HARMONIC Generator 300



(1) - Universal AC Mains Input
(2) - Power Entry Module
(3) - Protective Earth Connection to Chassis
(4) - Mains Fuses, 3.15A, 250V, IEC Type 'T'
(5) - DPDT Mains Switch

(6) - 48VDC Medical Grade Power Supply
(7) - Generator PCB
(8) - Isolated Transducer Drive / Patient Connection
(9) - Isolation Barriers
(10)- Functional Earth Connections to Chassis


BLACK
WHITE
GREEN
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WHITE
GREEN
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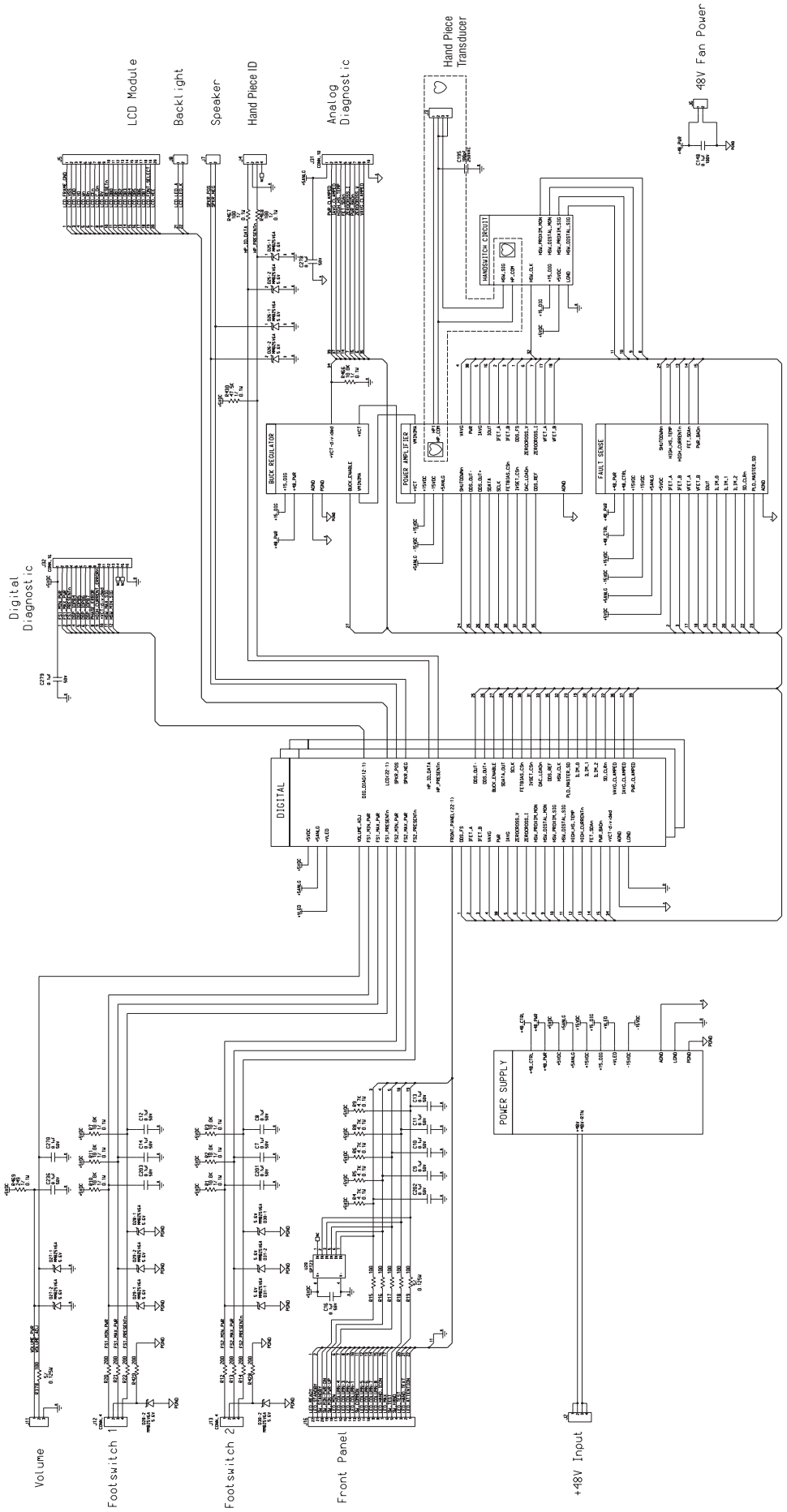
Parts List

The reference numbers below correspond to reference numbers on the Main Assembly Drawing on the previous page.

Reference No.	Part No.	Description
1	D06358P01	Fuse Label
2	D06363P01	Back Panel Label
3	3583.036	Bezel Sub-Assembly
4	3583.180	Cover Enclosure
5	3583.053	Cable Assembly, Hand Piece Receptacle
6	3583.060	Cable Assembly, Earth Terminal – Chassis
7	3583.061	Cable Assembly, Power Entry – Chassis
8	3583.062	Cable Assembly, Fuse Holder – AC Switch
9	3583.064	Cable Assembly, Volume Control – Generator Board
10	3583.065	Cable Assembly, Fan with Cable Assembly
11	3583.066	Cable Assembly, Speaker with Cable Assembly
12	3583.067	Cable Assembly, Power Supply – Generator Board
13	3583.070	Cable Assembly, Power Entry – Fuse Holder
14	3583.073	Cable Assembly, Foot Switch - Generator Board
15	3583.079	LCD Display PCB
16	3583.112	Wire Assembly, AC Switch – Power Supply
17	900-000526	Power Cord, 13 Amps, 125 Volts, 15 feet
18	3583.125	Label, Tamper Evident
19	600-000234	Power-on Rocker Switch
20	620-000243	Fuse 3.15 Amps, 250 Volts, Slo-Blo
21	640-000268	Ferrite Clamp/Bracket 279 @100MHz
22	700-001493	Hardware, Nut 8-32 (for fan assembly)
23	700-000394-2	Hardware, Phillips 8 – 32 x 5/16 (for ground to chassis)
24	700-000504-1	Hardware, Phillips 4 – 40 x 3/8
25	700-000884	Hardware, KNut 4-40
26	700-001497	Hardware, Ground Pin
27	700-001653	Hardware, Knob
28	700-001662	Hardware, Feet, Rubber Black, with screw
29	700-001663	Hardware, Fuseholder, 5 x 20 PNL MNT
30	953-45A067	Hardware, Phillips 8 – 32 x 5/16
31	700-001665	Hardware, Phillips 8 – 32 x 1-1/4 (for fan assembly)
32	700-001666	Hardware, Lockwasher, for Hand Piece
33	700-001667	Hardware, Grommet
34	700-001668	Hardware, Bushing (Wire Protectors)
35	700-001749	Hardware, Phillips 6 – 32 x 5/16
36	700-001767	Hardware, Hnut 3/4 – 16 x 7, 8 x 5/32
37	N/A	N/A
38	800-003007	Power Entry Module
39	875-000358	Power Supply, 48 Volt
N/A	950-000443	Packaging, Bag, Anti-Static 24 x 30; Pink
N/A	950-000530	Packaging, End Caps
N/A	950-000531	Packaging Carton, 18 x 19
43	700-000250	Hardware, Phillips 8 - 32 x 112, Secure Main Board
N/A	900-000266	Tystrap
45	3583.047	Generator PCB, Main
46	3583.042	Chassis Sub-Assembly
47	97-W13	CordSet Pack
48	N/A	Power Supply Fuse, 5 Amp, 250 Volt
N/A	3583.082-1.20	IC Containing Firmware 1.20

Note: Refer to Chapter 14 – System Specifications for torque requirements.


LCD Module
Backlight
Speaker
Hand Piece ID
Analog Diagnostic
Hand Piece Transducer
48V Fan Power
Digital Diagnostic
BUCK REGULATOR
POWER AMPLIFIER
HANDSWITCH CIRCUIT
FAULT SENSE
DIGITAL
POWER SUPPLY
Volume
Footswitch 1
Footswitch 2
Front Panel
+48V Input

Step 1 After the cover is taken off the generator, remove the IC chip that contains software 1.09 located in the socket marked U71 on the Main PCB. (This is best accomplished with a chip extractor like the one shown below).

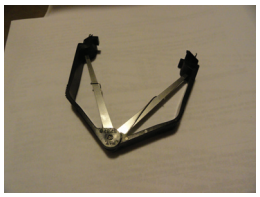


Figure A: Chip Extractor Tool

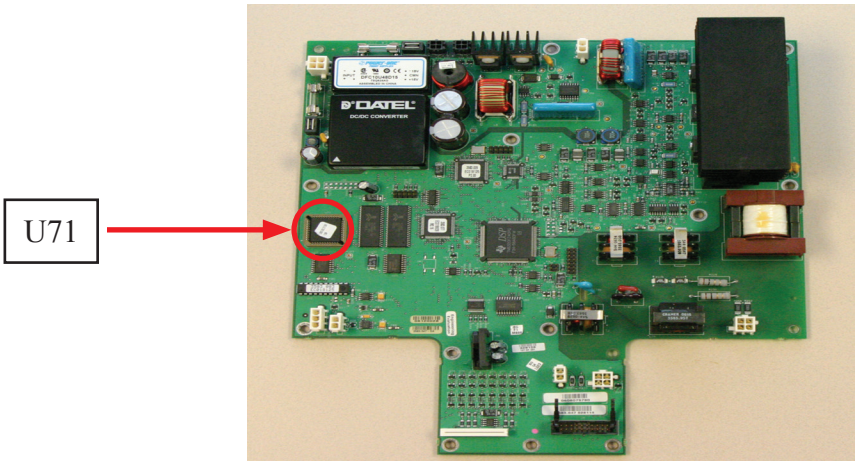
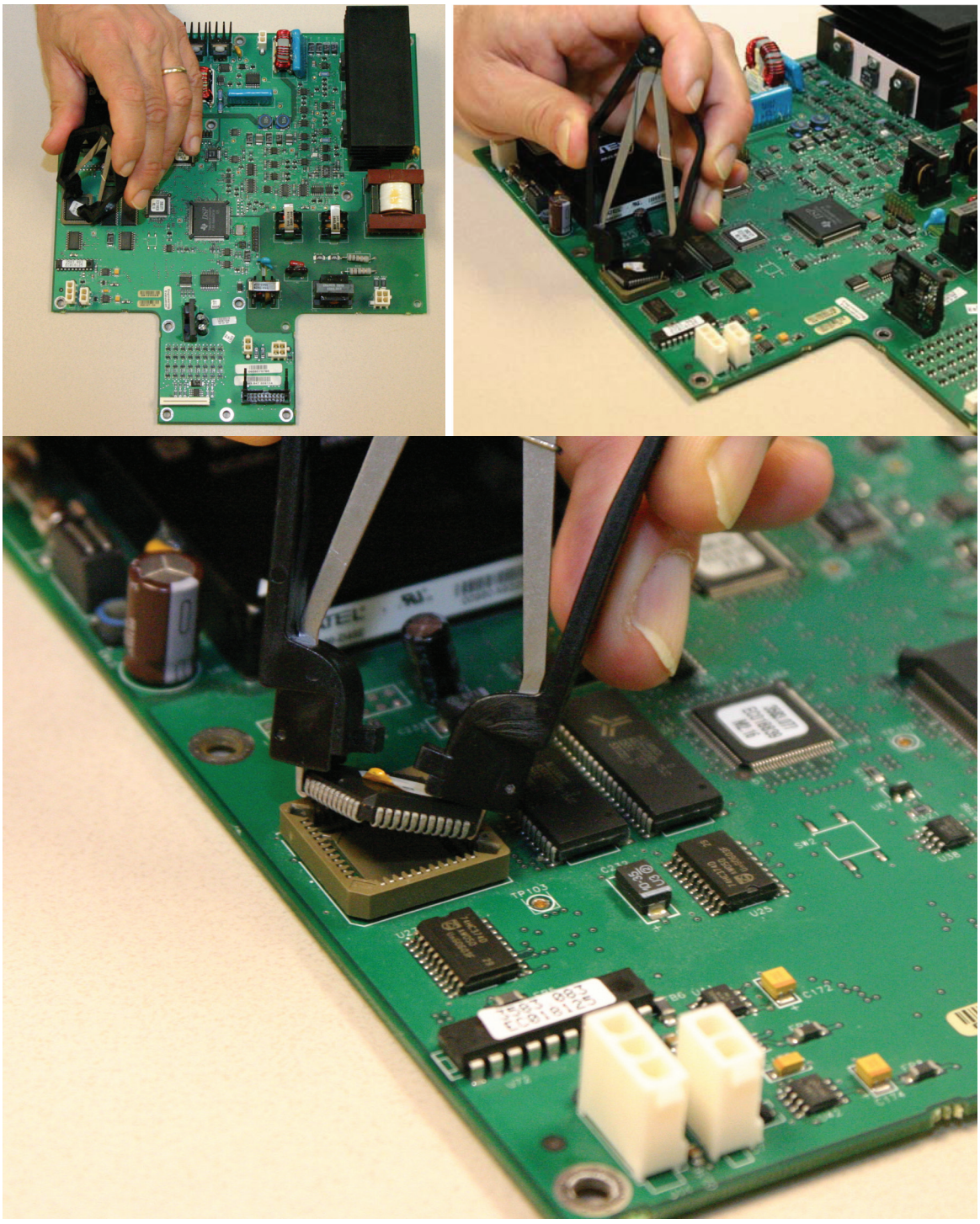
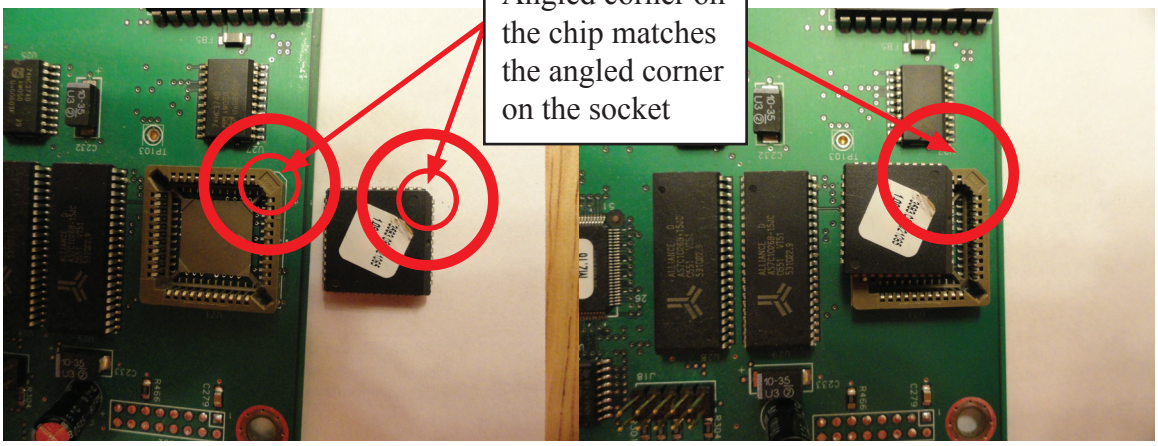


Figure B - Identifying U71 on Main PCB



Figures C, D & E - Removal of IC containing S/W 1.09

Step 2 **Install the IC with S/W 1.20. Note the orientation of the chip as shown in the figure below**. Make sure the chip is positioned *Flat or parallel* to the surface of the socket, then firmly press on the center of the chip to properly seat it inside the socket.



Figures F & G: Proper Chip Orientation

Step 3 Install the cover back on the Generator.

Step 4 Perform the function test called out on page 23 of this manual.

***Note 1*:** Calibration is not required when *only* performing a software upgrade.

***Note 2*:** Electrical safety testing is not required when *only* performing a software upgrade (although it may be performed per facility requirements).

P40401P06

REF
GEN04

USA REP

Ethicon Endo-Surgery, Inc.
Cincinnati, OH 45242-2839 USA
1-800-USE-ENDO

ETHICON ENDO-SURGERY, LLC
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